As filed with the U.S. Securities and Exchange Commission on February 14, 2025
Registration Statement No. 333-284362

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 4
to

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

RESHAPE LIFESCIENCES INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**26-1828101**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

18 Technology Dr, Suite 110
Irvine, California 92618
(949) 429-6680

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Paul F. Hickey
President and Chief Executive Officer
ReShape Lifesciences Inc.
18 Technology Dr, Suite 110
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(949) 429-6680

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Commission, acting pursuant to said section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholder may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 14, 2025

PRELIMINARY PROSPECTUS



Up to 1,779,360 Units, Each Unit Consisting of One Share of Common Stock or One Pre-funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

Up to 1,779,360 Shares of Common Stock Underlying the Pre-Funded Warrants

Up to 14,400,005 Shares of Common Stock Underlying the Warrants

ReShape Lifesciences Inc. (the "Company", "we", or "our") is offering on a best-efforts basis up to 1,779,360 units ("Units"), each Unit consisting of one share of our common stock, par value $0.001 per share (the "Common Stock"or "common stock") and one warrant (each, a "Warrant") to purchase one share of Common Stock, at an assumed public offering price of $2.81 per Unit, based upon the closing price of our Common Stock on The Nasdaq Capital Market on February 10, 2025.

The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The Warrants will be exercisable beginning on the effective date of such stockholder approvals as may be required by the applicable rules and regulations of the Nasdaq Capital Market (or any successor entity) to permit the exercise of the Warrants ("Warrant Stockholder Approval"). The Warrants will initially have an exercise price equal to no less than 100% and no more than 300% of the public offering price and will expire on later of (i) twelve (12) days after date of Warrant Stockholder Approval and (ii) the earlier of (x) the closing date of the transaction contemplated by the merger transaction described under "Prospectus Summary — Recent Developments — Pending Merger and Asset Sale" and (y) sixty (60) days after the date of Warrant Stockholder Approval. We have agreed not to consummate such merger transaction until at least 12 trading days after Warrant Stockholder Approval has been obtained. The Warrants will not be exercisable at the closing of this offering and may never become exercisable if the Warrant Stockholder Approval is not obtained. Therefore, the Warrants could expire worthless if the Warrant Stockholder Approval is not obtained in the future. The terms of the Warrants will include a potential one-time reset of the exercise price (subject to a floor of $1.25 per share) and number of shares of our Common Stock underlying the Warrants and an alternative cashless exercise option that are applicable after effective date of the Warrant Stockholder Approval as described under *"Description of the Securities We are Offering."* Under the alternative cashless exercise option under the Warrants, a Warrant holder could elect to receive 1.2 shares of common stock without the holder having to make any exercise payment. If the exercise price of the Warrants is reset to the floor price of $1.25 per share, then based on an assumed initial exercise price of $8.43 per share (equal to 300% of the assumed offering price per Unit) underlying the Warrants, the number of shares of Common Stock underlying each Warrant would be increased to 6.744 shares and, if a Warrant holder then elected the alternative cashless exercise option, they would receive 8.093 shares of Common Stock (equal to 1.2 times 6.744 shares). In that scenario, the maximum aggregate number of shares of Common Stock to be issued upon the alternative cashless exercise of the Warrants would be approximately 14,400,005 shares. As a result of the reset provisions in the Warrants, a higher initial exercise price of the Warrants could result in more shares of Common Stock being issued upon exercise (including the alternative cashless exercise) of the Warrants if the exercise price of the Warrants is reduced as a result of the reset provisions. Therefore, we do not expect to receive any cash proceeds from the exercise of the Warrants because it is highly unlikely that a Warrant holder will elect to pay an exercise price in cash to receive one share of common stock when they could elect the alternative cashless exercise option and pay no exercise price to receive 1.2 times the number of shares of common stock they would receive if they did pay an exercise price.

We are also offering to each purchaser of Units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock immediately following the consummation of this offering, the opportunity to purchase Units consisting of one pre-funded warrant (in lieu of one share of Common Stock, each a "Pre-funded Warrant"), and one Warrant. Subject to limited exceptions, a holder of Pre-funded Warrants will not have the right to exercise any portion of its Pre-funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, such limit may be increased to up to 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise. Each Pre-funded

Warrant will be exercisable for one share of Common Stock. The purchase price of each Unit including a Pre-funded Warrant will be equal to the price per Unit including one share of Common Stock, minus $0.001, and the remaining exercise price of each Pre-funded Warrant will equal $0.001 per share. The Pre-funded Warrants will be immediately exercisable (subject to the beneficial ownership cap) and may be exercised at any time until the earlier of (x) all of the Pre-funded Warrants are exercised in full and (y) the consummation of the merger transaction described under "Prospectus Summary — Recent Developments — Pending Merger and Asset Sale." For each Unit including a Pre-funded Warrant we sell (without regard to any limitation on exercise set forth therein), the number of Units including a share of Common Stock we are offering will be decreased on a one-for-one basis.

Our common stock is traded on the Nasdaq Capital Market under the symbol "RSLS." On February 11, 2025, the closing price for our common stock, as reported on the Nasdaq Capital Market, was $2.705 per share. There is no established trading market for the Warrants and Pre-funded Warrants and we do not intend to list the Warrants or the Pre-funded Warrants on any securities exchange or nationally recognized trading system.

The Units will be offered at a fixed price and are expected to be issued in a single closing. There is no minimum number of securities or minimum aggregate amount of proceeds for this offering to close. However, notwithstanding the foregoing, the shares of our Common Stock underlying any Warrants or Pre-funded Warrants will be offered on a continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended. This offering will be completed not later than February 18, 2025 and we will deliver all securities to be issued in connection with this offering delivery versus payment or receipt versus payment, as the case may be, upon receipt of investor funds received by us. Accordingly, neither we nor the placement agent have made any arrangements to place investor funds in an escrow account or trust account since the placement agent will not receive investor funds in connection with the sale of the securities offered hereunder.

We have engaged Maxim Group LLC (the "placement agent" or "Maxim") to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering, and the placement agent is not required to arrange the purchase or sale of any specific number or dollar amount of securities. Because there is no minimum offering amount required as a condition to closing in this offering, the actual offering amount, placement agent's fee and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts described throughout this prospectus. We have agreed to pay the placement agent, the placement agent fees set forth in the table below and to provide certain other compensation to the placement agent. See "Plan of Distribution" for more information regarding these arrangements.

You should read this prospectus, any applicable prospectus supplement and any related free writing prospectus carefully before you invest.

Investing in shares of our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 12 of this prospectus, as well as those risk factors described in any applicable prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Unit With Share of Common Stock	Per Unit With Share of Pre-Funded Warrant	Total[2]
Public offering price	$	$	$
Placement agent fees[1]	$	$	$
Proceeds, before expenses, to us	$	$	$

(1) The placement agent fees shall equal 7.0% of the gross proceeds of the securities sold by us in this offering. The placement agent will receive compensation in addition to the placement agent fees described above. See "Plan of Distribution" for a description of compensation payable to the placement agent.

(2) This assumes the full exercise of the Pre-funded Warrants.

We anticipate that delivery of the securities against payment will be made on or about [ ], 2025.

Maxim Group LLC

The date of this prospectus is , 2025.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 for the offering by us of shares of common stock.

You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus, even though this prospectus is delivered or our securities registered under the registration statement of which this prospectus forms a part are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions "*Where You Can Find Additional Information*" in this prospectus.

Neither we nor the placement agent have authorized anyone to provide any information or to make any representation other than those contained in this prospectus. You must not rely upon any information or representation not contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our securities other than the securities covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any securities of our company in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction

We obtained certain statistical data, market data and other industry data and forecasts used in this prospectus from publicly available information. While we believe that the statistical data, industry data, forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information.

This prospectus contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. Please read "*Cautionary Note Regarding Forward- Looking Statements*" and "*Risk Factors*".

Effective September 23, 2024, we effected a 1-for-58 reverse stock split of our issued and outstanding common stock (the "Reverse Stock Split"). All references to shares of our common stock in this prospectus refer to the number of shares of common stock after giving effect to the Reverse Stock Split and are presented as if the Reverse Stock Split had occurred at the beginning of the earliest period presented.

PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained in this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our securities. For a more complete understanding of our company and this offering, we encourage you to read and consider the more detailed information included in this prospectus, including risk factors, see "Risk Factors" beginning on page 12 of this prospectus, and our most recent consolidated financial statements and related notes.

Throughout this prospectus, the terms "we," "us," "our," "ReShape," and "our company" refer to ReShape Lifesciences Inc., a Delaware corporation, and its consolidated subsidiaries, unless the context requires otherwise.

About ReShape Lifesciences Inc.

ReShape Lifesciences Inc. is a premier physician-led weight-loss solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease throughout the care continuum.

Our current portfolio includes the U.S. Food and Drug Administration ("FDA") approved and reimbursed Lap-Band® and the recently approved Lap-Band® 2.0 FLEX systems, which provide minimally invasive, long-term treatment of obesity and is a safer surgical alternative to more invasive and extreme surgical stapling procedures such as the gastric bypass or sleeve gastrectomy.



ReShape's Pillars for Growth

In August of 2022, Paul F. Hickey joined ReShape as President and Chief Executive Officer. Under this new leadership, our company has pivoted its business strategy with the intent of helping to ensure growth and profitability. Our company has executed the following three growth strategies, or pillars for growth:

- **Growth Pillar I: Executing disciplined, metrics-driven business operations.**

In executing the first growth pillar, our company is focused on revenue growth and profitability. The timeline for profitability is dependent on many factors, including revenue growth from new product introductions, or strategic investments not yet foreseen.

This first growth pillar remains, in our company's opinion, paramount for ReShape to deliver shareholder value and, ultimately, profitability. Starting shortly after Mr. Hickey's appointment, ReShape has made several operational changes to help ensure future performance and return on investment by prioritizing investments supporting revenue growth.

Our company has prioritized investments, including marketing automation to support scalable lead acquisition, segmented consumer-centric messaging via an updated website for improved patient engagement, and a frictionless booking system with qualified providers. Early metrics from these marketing efforts have been shown to help increase Lap-Band procedures and ultimately revenue, despite the headwinds created by the widespread marketing and adoption of GLP-1 receptor agonists, including Wegovy, Ozempic, and Zepbound. Additionally, our company 2024 cost reduction plan, had led to approximately 41% lower operating expenses for the first nine months of the 2024, compared to last year, excluding one-time costs. Our company has also taken steps to right-size the organization in several areas to ensure sustainability and scalability.

- **Growth Pillar II: Expanding the product portfolio and future product pipeline.**

ReShape's second growth pillar is intended to further differentiate our company as a leading provider of innovative products and services to meet unmet customer needs. ReShape is committed to drive and scale its new product development and commercialization capacity, providing a cadence of new product introductions and revenue growth. The growth can either be through organic internal Research and Development efforts, or through strategic partnerships, mergers, or acquisitions. Key growth drivers within second growth pillar include:

Lap-Band 2.0 FLEX System — New product revenues for the Lap-Band 2.0 FLEX system ("Lap-Band 2.0"), for which our company received FDA approval during December 2023 and completed the first successful surgeries in early 2024. Similar to the current Lap-Band, the Lap-Band 2.0 is adjustable, postoperatively, to increase or decrease the opening of the band to optimize an individual's eating habits and comfort, thereby improving therapy effectiveness. At the same time, a new feature of the Lap-Band 2.0 is a band reservoir technology that serves as a relief valve. Pieces of food that are too large to pass through the narrowed passage, created by the current band, can pass through because the new feature allows the band to relax momentarily and then return to its resting diameter. This could potentially allow for increased Lap-Band constriction and resultant satiety, while helping to minimize discomfort from swallowing large pieces of food, which may otherwise require emergency in-office patient band adjustments. Based on customer feedback, Lap-Band 2.0 will allow us to engage new surgeons and reengage many of those who have used the Lap-Band, historically.

ReShape Obalon Balloon — The ReShape Obalon® Balloon system is the first and only swallowable, gas filled, FDA-approved balloon system. In 2023 our company established an OEM partnership with Biorad Medisys ("Biorad"), based in India that will support the successful relaunch and commercialization of the balloon system. We anticipate having access to the Obalon Balloon system late in 2025 for the distribution in the U.S. and other regions globally. In addition, the strategic partnership with Biorad contemplates potential manufacturing transfer of other products to further improve ReShape's overall gross margin.

DBSN Device — ReShape remains committed to furthering our proprietary Diabetes Bloc-Stim Neuromodulation (DBSNTM) technology that can potentially reduce the dependence on medications by those with type 2 diabetes. The DBSNTM device is a technology under development as a new treatment for type 2 diabetes mellitus. The device is expected to use bioelectronics to manage blood glucose in the treatment of diabetes and individualized 24/7 glucose control. Preclinical evidence on the DBSN device was presented at multiple conferences. The DBSN technology development has received approximately $1.15 million dollars of nondilutive NIH grant support.

- **Growth Pillar III: Ensuring that our portfolio spans the weight loss care continuum and is evidence based.**

ReShape's third growth pillar represents our company's commitment to collaborate with healthcare professionals worldwide and further develop evidence supporting ReShape's portfolio of treatment options. Aligned with goal of pillar three, in early 2023, ReShape established their first-ever global Scientific Advisory Board (SAB) to provide needed expertise and feedback on initiatives related to our company's growth pillars. The SAB is fully engaged in helping validate company strategies to collect and publish data on both our Lap-Band 2.0 and data on Lap-Band patients who are also using GLP-1s as a combination therapy. Combination therapies comprising GLP-1s and other gastric surgeries, including the Lap-Band, are being prescribed today, to help those who have plateaued with their weight loss.

Our Product Portfolio

Lap-Band System

The Lap-Band System is designed to provide minimally invasive long-term treatment of severe obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. Unlike other invasive anatomy altering procedures, the Lap-Band System is adjustable post-operatively via a saline-filled silicone band that is laparoscopically placed around the upper part of the stomach through small laparoscopic incisions, creating a small pouch at the top of the stomach, which slows the passage of food and creates a sensation of fullness. The procedure can normally be performed as an outpatient procedure and patients can go home the day of the procedure without the need for an overnight hospital stay.

Lap-Band 2.0 FLEX System

The Lap-Band 2.0 FLEX, like the original Lap-Band System, is designed to provide minimally invasive long-term treatment of severe obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. Unlike more invasive and anatomy altering surgeries, the Lap-Band 2.0 is adjustable postoperatively to increase or decrease the pressure to the band in order to optimize an individual's comfort and therapy effectiveness. The Lap-Band 2.0 system includes a FLEX reservoir technology designed to minimize postoperative in-office patient band adjustments, thereby potentially improving an individual's tolerance for the Lap-Band 2.0. As of October 2024, we have completed our early launch phase of the Lap-Band 2.0 FLEX and are analyzing data and metrics that will be used to support our widespread commercial launch. Additionally, we received approval for the Lap-Band® 2.0 FLEX from Health Canada, which represents yet another important growth catalyst for the Lap-Band franchise as we look to gain regulatory approvals world-wide.

ReShape Calibration Tubes

The ReShape Calibration tubes are multifunctional devices compared to reusable bougies and disposable gastric tubes. The Calibration tubes are designed to fit the lesser curvature of the stomach more easily and quickly reach the pylorus. In August of 2022, we announced FDA clearance of three new sizes — 32, 36, and 40 French — all designed to simplify bariatric procedures such as laparoscopic sleeve gastrectomy, gastric bypass, and adjustable gastric banding. During the first quarter of 2023, we fully released this product and continue to ramp production.

ReShape Obalon Balloon System

The FDA PMA approved Obalon Balloon System, is not currently manufactured and distributed for commercial sales, consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Obalon Navigation System console, has FDA PMA supplemental approval, is a combination of hardware and software used to dynamically track and display the location of the balloon during placement; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas.

DBSN Device

The DBSN device, that is not currently available for commercial sales, is a technology under development as a new treatment for type 2 diabetes mellitus (T2DM). It combines ReShape Lifesciences' proprietary Vagus Nerve Block (vBloc) technology platform in combination with Vagus nerve stimulation. This new dual Vagus nerve neuromodulation device selectively modulates vagal blocking and stimulation to the liver and pancreas to manage blood glucose. Our DBSN device is expected to use bioelectronics to manage blood glucose in treatment of diabetes and individualized 24/7 glucose control. The goal is to reduce costs of treatment and complications that arise from poorly controlled blood glucose and non-compliance to T2DM medication.

Recent Developments

Equity Line of Credit and Secured Convertible Note

On December 19, 2024, we entered into a common stock purchase agreement (the "Equity Purchase Agreement") with Ascent Partners Fund LLC ("Ascent") pursuant to which Ascent has agreed to purchase from us, at our direction from time to time, in our sole discretion, from and after the effectiveness of the definitive documentation (the "Effective Date"), and until the earlier of (i) the 36-month anniversary of the Effective Date or (ii) the termination of the Equity Purchase Agreement in accordance with the terms thereof (the "Commitment Period"), shares of our common stock having a total maximum aggregate purchase price of $5,000,000 (the "Purchase Shares"), upon the terms and subject to the conditions and limitations set forth therein. See the section titled "Description of Equity Financing Transaction" below for additional information.

In a private transaction, on October 16, 2024, we entered into a securities purchase agreement (the "SPA") with Ascent. Pursuant to the SPA, we agreed to issue to Ascent a senior secured convertible note in the aggregate original principal amount of $833,333.34 (the "Note"), and also issued to Ascent 7,983 shares of common stock as "commitment shares" to Ascent. On January 14, 2025, we entered into an amendment to the Note with Ascent to (a) extend the maturity date to the earlier of the closing of the Company's merger with Vyome or 90 days after the date of the amendment, (b) provide that Ascent would not be obligated to convert any part of the Note at the closing of the merger, (c) reduce the mandatory prepayment provision for funds raised by the Company in subsequent financings from 66% to 50%, and (d) require a $45,000 cash extension fee to be paid by the Company at the maturity of the Note. See the section titled "Description of Convertible Note Transaction" below for additional information.

Pending Merger and Asset Sale

On July 8, 2024, we entered into an Agreement and Plan of Merger ("Merger Agreement") with Vyome Therapeutics, Inc. ("Vyome") and Raider Lifesciences Inc., a Delaware corporation, and a direct, wholly owned subsidiary of ReShape ("Merger Sub"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions specified therein, Merger Sub shall be merged with and into Vyome, with Vyome surviving as a subsidiary of ReShape (the "Merger"). The combined company intends to change its name to Vyome Holdings, Inc. and will focus on Vyome's business of advancing the development of its immuno- inflammatory assets and on identifying additional opportunities between the world-class Indian innovation corridor and the U.S. market.

Simultaneously with the execution of the Merger Agreement, we entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Ninjour Health International Limited, a company incorporated under the laws of the United Kingdom ("Ninjour"). Pursuant to the Asset Purchase Agreement, and subject to the satisfaction or waiver of the conditions specified therein, we will sell substantially all of our assets (excluding cash) to Ninjour (or an affiliate thereof), and Ninjour will assume substantially all of our liabilities, for a purchase price of $5.16 million in cash, subject to adjustment based on ReShape's actual accounts receivable and accounts payable at the closing compared to such amounts as of March 31, 2024 (the "Asset Sale"). Ninjour is an affiliate of Biorad Medisys, Pvt. Ltd., which is party to a previously disclosed exclusive license agreement, dated September 19, 2023, with ReShape for ReShape's Obalon® Gastric Balloon System.

On October 1, 2024, we filed a Registration Statement on Form S-4 in connection with the Merger and Asset Sale, which we anticipate will close in the second quarter of 2025, assuming the conditions to closing are satisfied. On December 6, 2024, we filed an Amendment No. 1 to that Registration Statement on Form S-4 and on January 15, 2025 we filed an Amendment No. 2 to that Registration Statement on Form S-4.

We entered into the Equity Purchase Agreement and Convertible Note transactions in order to fund our operations through the closing of the Merger and Asset Sale. The description of our business set forth above reflects our current business operations, but if the Merger and Asset Sale are completed, we will sell substantially all of our assets to Ninjour Health International Limited (or an affiliate thereof) and the combined company following the Merger intends to focus on Vyome's business. However, the completion of the Merger and Asset Sale both remain subject to a number of conditions to closing, including the approval

of our stockholders and, with respect to the Merger, the approval of the Nasdaq Stock Market, and there can be no assurance that the Merger and Asset Sale will be consummated. Failure to complete the Merger and Asset Sale could negatively impact our future operations, financial results and stock price.

Reverse Stock Split

Effective September 23, 2024, we effected a 1-for-58 reverse stock split of our issued and outstanding common stock (the "Reverse Stock Split"). All references to shares of our common stock in this prospectus refer to the number of shares of common stock after giving effect to the Reverse Stock Split and are presented as if the Reverse Stock Split had occurred at the beginning of the earliest period presented.

Our Corporate Information

We were incorporated under the laws of Delaware on January 2, 2008. On June 15, 2021, we completed a merger with Obalon Therapeutics, Inc. Pursuant to the merger agreement, a wholly owned subsidiary of Obalon merged with and into ReShape, with ReShape surviving the merger as a wholly owned subsidiary of Obalon. As a result of the merger, Obalon, the parent company, was renamed "ReShape Lifesciences Inc." and ReShape was renamed ReShape Weightloss Inc. ReShape Lifesciences shares of common stock trade on the Nasdaq under the symbol RSLS.

Our principal executive offices are located at 18 Technology Drive, Suite 110, Irvine, California 92618, and our telephone number is (949) 429-6680. Our website address is *www.reshapelifesciences.com*. The information on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

THE OFFERING

Issuer:	ReShape Lifesciences Inc.
Securities being offered:	Up to 1,779,360 Units, based on an assumed offering price of $2.81 per Unit, each Unit consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock. We are also offering to each purchaser whose purchase of Units consisting of shares of Common Stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, Units, including Pre-funded Warrants, in lieu of shares of Common Stock that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding Common Stock. Subject to limited exceptions, a holder of Pre-funded Warrants will not have the right to exercise any portion of its Pre-funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise. Each Pre-funded Warrant will be exercisable for one share of our Common Stock. The purchase price of each Unit including a Pre-funded Warrant will equal the price per Unit in which the shares of Common Stock and accompanying Warrants are being sold to the public in this offering, minus $0.001, and the exercise price of each Pre-funded Warrant will be $0.001 per share. The Pre-funded Warrants are immediately exercisable and may be exercised at any time until the earlier of (x) all of the Pre-funded Warrants are exercised in full and (y) the consummation of the Merger. This offering also relates to the shares of Common Stock issuable upon exercise of any Pre-funded Warrants sold in this offering. For each Pre-funded Warrant we sell, the number of shares of Common Stock we are offering will be decreased on a one-for-one basis.
Description of the Warrants:	Each Warrant is initially exercisable at a price equal to not less than 100% and not more than 300% of the Unit offering price. The Warrants will be exercisable on effective date of Warrant Stockholder Approval and will expire on the later of (i) twelve (12) days after date of Warrant Stockholder Approval and (ii) the earlier of (x) the closing date of the transaction contemplated by the Merger and (y) sixty (60) days after the date of Warrant Stockholder Approval. The exercise price of the Warrant will be subject to adjustment on the date that is four trading days after Warrant Stockholder Approval is obtained (the "Reset Date"), if the lowest volume weighted average price ("VWAP") for our Common Stock during the period beginning four trading days prior to the effective date of Warrant Stockholder Approval and ending four trading days after the effective date of Warrant Stockholder Approval is lower than the then exercise price of the Warrants, in which case, on the Reset Date, the exercise price of the Warrants will be reset (subject to a floor of $1.25 per share) to equal such lowest VWAP and the number of shares of Common Stock underlying the Warrants will be increased so that the reset exercise price multiplied by increased number of

	shares equals the aggregate proceeds that would have resulted from the full exercise of the Warrants immediately prior to the Reset Date. The Warrants also contain certain mechanisms for cashless exercise, including alternative cashless exercise pursuant to which holders of Warrants have the option, upon exercise and for no additional cash consideration, to receive an aggregate number of shares of Common Stock equal to the product of (x) the aggregate number of shares of Common Stock that would be issuable upon a cash exercise of the Warrant and (y) 1.2. See "Description of Securities We are Offering — Warrants." Because the Warrants are not exercisable until the effective date of the Warrant Stockholder Approval, the Warrant may never become exercisable. See "Risk Factors" for more information regarding the exercisability of the Warrants. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants.
Assumed public offering price Unit:	$2.81 per Unit (minus $0.001 with respect to any Unit that includes a Pre-Funded Warrant).
Common stock outstanding prior to this offering:	729,980 shares[(1)]
Common stock to be outstanding after this offering:	2,056,240 shares
Best efforts offering:	We have agreed to offer and sell the securities offered hereby directly to the purchasers. We have retained Maxim Group LLC to act as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. The placement agent is not required to buy or sell any specific number of the securities offered hereby. See "Plan of Distribution" beginning on page [ ] of this prospectus.
Placement agent's warrants:	We have agreed to issue to the placement agent (or its permitted assignees) warrants to purchase a number of shares of Common Stock equal to 5.0% of the total number of Units being sold in this offering. The placement agent's warrants will be substantially similar to the Warrants issued to the purchasers hereunder except that the exercise price will be $[ ] per share (being equal to 120% of the public offering price of each Unit in this offering). Such warrant will be subject to FINRA Rule 5110(e)(1) in that, except as otherwise permitted by FINRA rules, for a period of 180 days from the commencement of sales of this offering, the warrant shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person except as permitted by FINRA Rule 5110(e)(2). See the form of placement agent's warrant filed as an exhibit hereto for a complete description of the terms of the placement agent's warrants. The placement agent's warrants and the shares of Common Stock underlying the placement agent's warrants are being registered on the registration statement of which this prospectus is a part.

Use of proceeds:	Assuming all of the securities we are offering in this offering are sold, we estimate that our net proceeds from this offering will be approximately $4,450,000. However, this is a best efforts offering, with no minimum number of securities or amount of proceeds as a condition to closing, and we may not sell all or any of these securities offered pursuant to this prospectus; as a result, we may receive significantly less in net proceeds. We intend to use the net proceeds from this offering for general corporate purposes, including expenses related to our previously announced proposed merger with Vyome Therapeutics, Inc. and sale of substantially all of our assets to Ninjour Health International Limited, provided that under the terms of the Securities Purchase Agreement for the Convertible Note transaction with Ascent, we must use up to 50% of the net proceeds from any issuance of capital stock to prepay the amount we owe to Ascent under the Convertible Note. See section titled "*Use of Proceeds*" for more information.
Risk factors:	You should read the "*Risk Factors*" beginning on page [ ] of this prospectus for a discussion of factors to consider carefully before deciding to invest in our securities.
Stock exchange listing:	Our common stock is listed on the Nasdaq Capital Market under the symbol "RSLS." On February 10, 2025, the last reported sale price of our common stock on the Nasdaq Capital Market was $2.705 per share. There are no established public trading markets for the Pre-funded Warrants or the Warrants, and we do not expect such markets to develop. We do not intend to list the Pre-funded Warrants or the Warrants on any securities exchange or other trading market.

Unless otherwise indicated, this prospectus assumes no issuance of Pre-funded Warrants in connection with this offering or exercise of any Warrants.

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(1) The above discussion and table are based on 729,980 shares of common stock outstanding as of February 10, 2025 and excludes:

- 144 shares of common stock issuable upon the exercise of outstanding options granted as of February 10, 2025 under our equity incentive plans at a weighted average exercise price of $34,101 per share;
- 81,384 shares of common stock issuable upon the exercise of outstanding warrants issued as of February 10, 2025;
- 8 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of February 10, 2025; and
- 10 shares of our common stock issuable upon the conversion of 95,388 shares of series C convertible preferred stock outstanding as of February 10, 2025.

SUMMARY RISK FACTORS

The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, results of operations, financial condition, cash flows, prospects and/or the price of our outstanding securities and make an investment in our securities speculative or risky. You should read this summary together with the more detailed description of each risk factor contained below.

Risks Related to this Offering

- Management will have broad discretion as to the use of the net proceeds from this offering, and we may not use these proceeds effectively.
- This is a best efforts offering, and no minimum number or dollar amount of securities is required to be sold, and we may not raise the maximum amount we are offering.
- You will experience immediate dilution in the net tangible book value per share of the Common Stock you purchase, and may experience additional dilution in the future.
- There is no public market for the Warrants or Pre-funded Warrants being offered by us in this offering.
- If the Warrants are exercised by way of an alternative cashless exercise, especially after the reset date stockholders may suffer substantial dilution.
- The Warrants are not exercisable unless and until Warrant Stockholder Approval is obtained from our stockholders. Further, even if we obtain Warrant Stockholder Approval, the Warrants may only be exercisable for a limited period of time.

Risks Related to our Business and Industry

- If we are unable to either substantially improve our operating results or obtain additional financing, we may be unable to continue as a going concern.
- We have recently undertaken a cost reduction plan and reorganization, and may do so again in the future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits therefrom.
- We may be unable to attract and retain management and other personnel we need to succeed.
- We cannot assure you that we will ever generate substantial revenue or be profitable.
- Previously, we recorded a non-cash indefinite-lived intangible and definite-lived assets impairment loss, which significantly impacted our results of operations, and we may be exposed to additional impairment losses that could be material.

Risks Related to Outstanding Secured Convertible Note and Proposed Equity Line of Credit

- The sale of issuance of our common stock to Ascent under our proposed equity line of credit transaction may cause dilution and the sale of the shares of common stock acquired by Ascent, or the perception that such sales may occur, could cause the price of our common stock to fall.
- Ascent will pay less than the then-prevailing market price for our common stock, which could cause the price of our common stock to decline.
- The Note is fully secured by collateral of ReShape and our subsidiaries and Ascent, as our senior secured lender, may exercise its right in the event of default.
- It is not possible to predict the actual number of shares we will sell under the Equity Purchase Agreement to Ascent or the actual gross proceeds resulting from those sales.
- Our commitment to issue shares of our common stock pursuant to the terms of the Equity Purchase Agreement could encourage short sales by third parties, which could contribute to the future decline of our stock price.

Risks Related to the Pending Merger

- Fluctuations in the market price of our common stock will affect the value of the Merger Consideration.
- The Exchange Ratio in the Merger Agreement is subject to adjustment based on ReShape's net cash as of a determination date prior to completion of the Merger, which could dilute further the ownership of either the ReShape or Vyome stockholders in the combined company.
- The ownership percentages of the ReShape and Vyome stockholders, respectively, that will result from the Exchange Ratio in the Merger Agreement are calculated prior to the completion of the Concurrent Financing, which could dilute further the ownership of the ReShape stockholders in the combined company.
- The Merger may not be consummated unless important conditions are satisfied or waived and there can be no assurance that the Merger will be consummated.
- Although an application has been filed to list the ReShape Shares on The Nasdaq Capital Market, there can be no assurance that the common stock will be so listed or, if listed, that the Combined Company will be able to comply with the continued listing standards.

Risks Related to the Business of the Combined Company After the Merger

- Combining the two companies may be more difficult, costly or time consuming than expected, and the Combined Company may not realize all of the anticipated benefits of the Merger.
- ReShape and Vyome will incur substantial direct and indirect costs as a result of the Merger and the Combined Company will incur substantial direct and indirect costs following the Merger.
- Both ReShape and Vyome have operated with a loss and negative cash flows for the entirety of their existence and it is expected the Combined Company will have to raise significant capital in the future that could be dilutive to stockholders of the Combined Company.
- If the perceived benefits of the Merger do not meet the expectations of investors or securities analysts, the market price of ReShape's securities or, following the Merger, Vyome Holdings, Inc. securities, may decline.

Risks Associated with Development and Commercialization of ReShape's Lap-Band System, Lap-Band 2.0 System, Obalon Balloon System, and the DBSN Device

- Our efforts to increase revenue from our Lap-Band System, Lap-Band 2.0 System, and commercialize our DBSN device and expanded line of bariatric surgical accessories, including ReShape Calibration Tubes, may not succeed or may encounter delays which could significantly harm our ability to generate revenue.
- We may not be able to obtain required regulatory approvals for our DBSN device in a cost-effective manner or at all, which could adversely affect our business and operating results.
- We depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

Risks Related to our Intellectual Property

- If we are unable to obtain or maintain intellectual property rights relating to our technology and neuroblocking therapy, the commercial value of our technology and any future products will be adversely affected and our competitive position will be harmed.
- We may lose important patents or patent rights if we do not timely pay required patent fees or annuities.

- Many of our competitors have significant resources and incentives to apply for and obtain intellectual property rights that could limit or prevent our ability to commercialize our current or future products in the United States or abroad.

Risks Relating to Ownership of our Common Stock

- The trading price of our common stock has been volatile and is likely to be volatile in the future.
- Sales of a substantial number of shares of our common stock in the public market by existing stockholders, or the perception that they may occur, could cause our stock price to decline.
- We have a significant number of outstanding warrants, which may cause significant dilution to our stockholders, have a material adverse impact on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings.

Risks Related to our Asset Sale

- While the ReShape Asset Sale is pending, it creates unknown impacts on ReShape's future which could materially and adversely affect its business, financial condition and results of operations.
- The failure to consummate the ReShape Asset Sale may materially and adversely affect ReShape's business, financial condition and results of operations.
- The Merger may be consummated despite the ReShape Asset Sale not closing under certain circumstances.
- The completion of the Asset Sale is contingent upon completion of the Merger.

RISK FACTORS

An investment in our securities is speculative and involves a high degree of risk and uncertainty. You should carefully consider the risks described below, together with the other information contained in this registration statement, including the consolidated financial statements and notes thereto, before deciding to invest in our securities. The occurrence of any of the events described below could have a material adverse effect on our business, financial condition, results of operations, cash flows, prospects or the value of our common stock. These risks are not the only ones that we face. Additional risks not currently known to us or that we currently deem immaterial also may impair our business.

Risks Related to Outstanding Secured Convertible Note and Proposed Equity Line of Credit

The sale or issuance of our common stock to Ascent may cause dilution and the sale of the shares of common stock acquired by Ascent, or the perception that such sales may occur, could cause the price of our common stock to fall.

The purchase price for the shares that we may sell to Ascent under the Equity Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

Subject to the terms of the Equity Purchase Agreement, we generally have the right to control the timing and amount of any future sales of our shares to Ascent. The extent to which we rely on Ascent as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources and other factors to be determined by us. We may ultimately decide to sell to Ascent all, some, or none of the shares of our common stock that may be available for us to sell pursuant to the Equity Purchase Agreement. When we sell shares to Ascent, after Ascent has acquired the shares, Ascent may resell all or some of those shares at any time or from time to time in its discretion. Therefore, sales to Ascent by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Ascent, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Ascent will pay less than the then-prevailing market price for our common stock, which could cause the price of our common stock to decline.

The purchase price of our common stock to be sold to Ascent under the Equity Purchase Agreements is derived from the market price of our common stock on Nasdaq. Shares to be sold to Ascent pursuant to the Equity Purchase Agreement will be purchased at a discounted price. We may effect sales to Ascent at a purchase price per share equal to 93% of the volume-weighted average price ("VWAP") of the common stock on the trading day prior to each closing; provided, that if 93% the lowest VWAP in the four trading days following such closing is lower than such price per share, then, as a "true-up", we shall issue additional shares of common stock to Ascent so as to ensure that the total number of shares received by Ascent is equal to the number it would have received for the aggregate purchase price paid at such closing if the shares of common stock had been valued at such lower number. See section entitled "*Description of Equity Financing Transaction*" for more information.

As a result of this pricing structure, Ascent may sell the shares they receive immediately after receipt of such shares, which could cause the price of our common stock to decrease.

The Note is fully secured by collateral of ReShape and our subsidiaries and Ascent, as our senior secured lender, may exercise its rights in the event of default.

The Note is fully secured by collateral of ReShape and our subsidiaries The security interest in favor of Ascent, as collateral agent, covers substantially all assets of ReShape including, without limitation, the intellectual property, trademark, and patent rights of ReShape. The parties entered into a Security Agreement and certain intellectual property security agreements granting such security interest in favor of Ascent. If an event of default is triggered and we do not obtain a waiver, Ascent can, among other things, accelerate the

entire outstanding amount of the debt and exercise its remedies, including foreclosure, as secured party on our assets and the assets of our subsidiaries, which could significantly deplete our resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent, which could prevent us from completing our proposed Merger and Asset Sale.

We will require additional financing to sustain our operations, without which we may not be able to continue operations, and the terms of subsequent financings may adversely impact our stockholders.

The extent we rely on Ascent as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working and other capital from other sources. If obtaining sufficient funding from Ascent were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working and other capital needs. Even if we were to sell to Ascent all of the shares of common stock available for sale to Ascent under the Equity Purchase Agreement, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences may be a material adverse effect on our business, operating results, financial condition and prospects. Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, convertible debt or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

Our management will have broad discretion over the use of the net proceeds from our sale of shares of common stock to Ascent, and you may not agree with how we use the proceeds, and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from our sale of shares of common stock to Ascent, and we could use them for purposes other than those contemplated at the time of commencement of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of those net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest those net proceeds in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flows.

It is not possible to predict the actual number of shares we will sell under the Equity Purchase Agreement to Ascent, or the actual gross proceeds resulting from those sales.

Because the purchase price per share to be paid by Ascent for the shares of common stock that we may elect to sell to Ascent under the Equity Purchase Agreement, if any, will fluctuate based on the market prices of our common stock during the applicable period for each purchase made pursuant to the Equity Purchase Agreement, if any, it is not possible for us to predict, as of the date of this prospectus and prior to any such sales, the number of shares of common stock that we will sell to Ascent under the Equity Purchase Agreement, the purchase price per share that Ascent will pay for shares purchased from us under the Equity Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Ascent under the Equity Purchase Agreement, if any.

Investors who buy shares at different times will likely pay different prices.

Pursuant to the Equity Purchase Agreement, we will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold to Ascent. If and when we do elect to sell shares of our common stock to Ascent pursuant to the Equity Purchase Agreement, after it has acquired such shares, Ascent may resell all, some or none of such shares at any time or from time to time in its discretion and at different prices. As a result, the other investors who purchase shares from Ascent in this offering at different

times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results.

Our commitment to issue shares of common stock pursuant to the terms of the Equity Purchase Agreement could encourage short sales by third parties, which could contribute to the future decline of our stock price.

Our commitment to issue shares of common stock pursuant to the terms of the Equity Purchase Agreement has the potential to cause significant downward pressure on the price of our common stock. In such an environment, short sellers may contribute to or exacerbate any decline of our stock price. If there are significant short sales of our common stock, the share price of our common stock may decline more than it would in an environment without such activity. This may cause other holders of our common stock to sell their shares. If there are many more shares of our common stock on the market for sale than the market will absorb, the price of our common stock will likely decline.

Although pursuant to the Equity Purchase Agreement and during the term thereof, Ascent shall not participate in short sales of our common stock or engage in hedging transactions, other third party investors may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. Such third-party investors may also loan or pledge shares of our common stock to broker-dealers that in turn may sell such shares. Such activity could cause a decline in the market price of the shares of our common stock.

Risks Related to the Pending Merger

Fluctuations in the market price of our common stock will affect the value of the Merger Consideration.

At the effective time of the Merger with Vyome (the "Effective Time"), each share of Vyome common stock and preferred stock (together, the "Vyome Shares") (other than the shares that are owned by ReShape, Vyome, or Merger Sub and shares that will be subject to a put-call option agreement with certain stockholders of Vyome and Vyome Therapeutics Limited ("Vyome India") who are located in India) will be converted into the right to receive a number of shares of our common stock ("ReShape Shares"), according to a ratio (the "Exchange Ratio") determined at least 10 days prior (the "Determination Date") to a special meeting of our stockholders (the "ReShape Special Meeting") that will result in the holders of such Vyome Shares owning 91.62% of the outstanding shares of the combined company ("Combined Company Shares") immediately after the effective time of the Merger, subject to adjustment based on ReShape's net cash is greater than or less than $5 million; provided that the shares to be received by certain stockholders of Vyome and Vyome India located in India shall be subject to the put-call option agreements with the combined company ("Combined Company"). The Exchange Ratio remains subject adjustment based on the actual shares outstanding, and ReShape's actual net cash, as of the Determination Date.

Because the exact number of ReShape Shares that will be issued in exchange for each Vyome Share (the "Merger Consideration") will not be determined until a later date, the market value of the Merger Consideration that Vyome stockholders will receive will depend both on the number of ReShape Shares to be issued and the price per ReShape Share at the Effective Time. The exact number of ReShape Shares to be Vyome and the market price per ReShape Share will not be known at the time of the ReShape Special Meeting and may be less or more than the current market price or the market price at the time of the ReShape Special Meeting.

The exact dollar value of the ReShape Shares that the Vyome stockholders and the ReShape stockholders will hold upon consummation of the Merger will not be known at the time of the ReShape Special Meeting and may be greater than, the same as or less than the current market price of ReShape Shares at the time of the ReShape Special Meeting. The market price of the ReShape Shares is subject to general price fluctuations in the market for publicly traded equity securities and has experienced volatility in the past and may vary significantly from the date of the ReShape Special Meeting. As a result of these fluctuations, the value of the Merger Consideration will also vary.

Stock price changes may result from a variety of factors, including general market, industry and economic conditions, changes in the respective businesses, operations and prospects of ReShape, regulatory considerations, results of the ReShape Special Meeting, announcements with respect to the Merger or any

of the foregoing, and other factors beyond the control of ReShape. You should obtain current market price quotations for ReShape Shares, but as indicated above, the price at the time the Merger is consummated may be greater than, the same as or less than such price quotations.

The Exchange Ratio in the Merger Agreement is subject to adjustment based on ReShape's net cash as of a determination date prior to completion of the Merger, which could dilute further the ownership of either the ReShape or Vyome stockholders in the Combined Company.

The Exchange Ratio in the Merger Agreement is subject to potential adjustment depending upon the amount of "net cash" of ReShape, as defined in the Merger Agreement and generally consisting of ReShape's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the Merger. If ReShape has more or less than $5.0 million of net cash as of the determination date, then the percentage ownership of the current ReShape stockholders will be increased or decreased on a pro rata basis. ReShape currently expects its net cash to be less than $5.0 million as of the determination date. In addition, one of the conditions to Vyome's obligations to complete the merger is ReShape's net cash must be at least $1,325,000 and if the closing occurs after July 31, 2024, with the minimum amount of ReShape's net cash being reduced by $175,000 on the first day of each month beginning on August 1, 2024. The items that will constitute ReShape's net cash at the determination date set forth in the Merger Agreement are subject to a number of factors, some of which are outside the control of ReShape.

The ownership percentages of the ReShape and Vyome stockholders, respectively, that will result from the Exchange Ratio in the Merger Agreement are calculated prior to the completion of the Concurrent Financing, which could dilute further the ownership of the ReShape stockholders in the Combined Company.

The pro forma ownership percentages of the ReShape and Vyome stockholders of the Combined Company of 8.38% and 91.62%, respectively, subject to adjustment, is prior to taking into account the purchase by certain accredited investors of up to $7.3 million in securities of ReShape, Vyome and Vyome India (the "Concurrent Financing"). Therefore, the actual ownership percentages will be different following the completion of the Concurrent Financing and, because certain of the investors in the Concurrent Financing are existing Vyome stockholders, the actual ownership percentage of the ReShape stockholders will be decreased compared to that of the Vyome stockholders after the closing of the Concurrent Financing. Solely for purposes of illustration, assuming the market price of the common stock of the Combined Company immediately following completion of the Merger is $10.00 per share, the shares of common stock to be issued in the Concurrent Financing would be sold at a price of $7.00 per share (reflecting a 30% discount to the market price). Therefore, if $6.0 million in shares of common stock of the Combined Company and up to $1.0 million of shares in Vyome India are sold immediately following completion of the Merger as part of the Concurrent Financing, and ReShape's net cash is $975,000, the Combined Company would issue approximately 538,875 shares of common stock immediately after completion of the Merger. Based on those assumptions, and assuming the actual ownership percentage of the ReShape stockholders of the Combined Company prior to the Concurrent Financing is 11.1%, the shares issued in the Concurrent Financing would reduce the ownership percentage of the ReShape stockholders of the Combined Company to approximately 7.8%.

The Merger may not be consummated unless important conditions are satisfied or waived and there can be no assurance that the Merger will be consummated.

The Merger Agreement contains a number of conditions that must be satisfied or waived (to the extent permitted by applicable law) to consummate the Merger. Those conditions include, among others:

- approval of the issuance of the ReShape Shares and the sale of ReShape's assets (the "Asset Sale") by the ReShape stockholders;
- the absence of any adverse law or order promulgated, entered, enforced, enacted, or issued by any government entity that prohibits, restrains, or makes illegal the consummation of the Merger or the other transactions contemplated by the Merger Agreement;
- the effectiveness of a registration statement on Form S-4 under the Securities Act of 1933, as amended (the "Securities Act"), which was initially filed by ReShape on October 1, 2024, and the

absence of any stop order issued by the Securities and Exchange Commission (the "SEC") suspending the use of such registration statement;

- the ReShape Shares to be issued in the Merger being approved for listing on The Nasdaq Capital Market and approval of the Combined Company's continued listing on The Nasdaq Capital Market (certain risks related to obtaining such approvals are described below);
- subject to certain materiality exceptions, the accuracy of certain representations and warranties of each of Vyome and ReShape contained in the Merger Agreement and the compliance by each party with the covenants contained in the Merger Agreement; and
- the absence of a material adverse effect with respect to each of Vyome and ReShape.

These conditions to the consummation of the Merger may not be satisfied or waived (to the extent permitted by applicable law) and, as a result, the Merger may not be consummated at the time expected, or at all. In addition, ReShape or Vyome may elect to terminate the Merger Agreement in certain other circumstances.

Although an application has been filed to list the ReShape Shares on The Nasdaq Capital Market, there can be no assurance that the common stock will be so listed or, if listed, that the Combined Company will be able to comply with the continued listing standards.

Nasdaq has determined that the proposed transaction constitutes a business combination that results in a change of control pursuant to its listing rules. Accordingly, the Combined Company will be required to satisfy all of Nasdaq's initial listing criteria and to complete Nasdaq's initial listing process in order for the ReShape Shares to be listed on Nasdaq. An application to list the ReShape Shares on The Nasdaq Capital Market upon consummation of the Merger has been filed as required by The Nasdaq Capital Market.

Nasdaq's approval of the listing application is a condition to the closing of the Merger and while ReShape and Vyome can each terminate the Merger Agreement if the condition is not satisfied under certain circumstances (in which case, a $1.0 million termination fee may be payable to the terminating party), the parties can also each choose to waive the condition and consummate the Merger without Nasdaq's approval of the listing application. In the event ReShape and Vyome waive that condition and consummate the Merger without Nasdaq's approval of the listing application, the Combined Company would not be listed on The Nasdaq Capital Market.

In addition, if after listing, The Nasdaq Capital Market delists the ReShape Shares from trading on its exchange for failure to meet the continued listing standards, the Combined Company and its stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for its securities;
- a determination that its common stock is a "penny stock" which will require brokers trading in its common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for its common stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The Merger Agreement contains provisions that could discourage a potential competing acquirer of either ReShape or Vyome.

The Merger Agreement contains "no shop" provisions that restrict each of Vyome's and ReShape's ability to solicit, initiate or knowingly encourage and induce, or take any other action designed to facilitate competing third-party proposals relating to a merger, reorganization or consolidation of the company or an acquisition of the company's stock or assets. In addition, the other party generally has an opportunity to offer to modify the terms of the Merger in response to any competing acquisition proposals before the board of directors of the company that has received a third-party proposal may withdraw or qualify its recommendation with respect to the Merger.

The Merger Agreement does not permit either Vyome or ReShape to terminate the Merger Agreement in order to pursue a superior proposal. These provisions could discourage a potential third-party acquirer that might have an interest in acquiring all or a significant portion of Vyome or ReShape from considering or proposing an acquisition, even if it were prepared to pay consideration with a higher per share cash or market value than the market value proposed to be received or realized in the Merger.

The pendency of the Merger could materially adversely affect the business, financial condition, results of operations or cash flows of ReShape or Vyome.

The announcement and pendency of the Merger could disrupt ReShape's or Vyome's businesses, in any of the following ways, among others:

- ReShape's employees are not expected to continue to be employed by the Combined Company, which might adversely affect ReShape's ability to retain its employees;
- the attention of ReShape management or Vyome management may be directed toward completion of the Merger and, in the case of ReShape, the Asset Sale, integration planning and transaction-related considerations and may be diverted from the company's day-to-day business operations and, following the completion of the Merger, the attention of the Combined Company's management may also be diverted to such matters;
- vendors, suppliers, business partners or others may seek to modify or terminate their business relationship with ReShape or Vyome or the Combined Company following completion of the Merger;
- ReShape or Vyome, or the Combined Company following completion of the Merger, and their respective directors could become subject to lawsuits relating to the Merger; and
- ReShape or Vyome may experience negative reactions from their stockholders and the medical community, among others.

These disruptions could be exacerbated by a delay in the completion of the Merger or termination of the Merger Agreement. Additionally, if the Merger is not consummated, each company will have incurred significant costs and diverted the time and attention of management. A failure to consummate the Merger may also result in negative publicity, reputational harm, litigation against ReShape or Vyome or their respective directors and officers, and a negative impression of the companies in the financial markets. The occurrence of any of these events individually or in combination could have a material adverse effect on either or both companies' financial statements and ReShape's stock price.

In addition, the Merger Agreement restricts Vyome and ReShape from taking certain actions until the Effective Time without the consent of the other party, including, among others: the payment of dividends; the issuance of equity (including certain equity incentive awards); certain increases to employee compensation and benefits; capital expenditures; the incurrence of indebtedness; acquisitions and divestitures; and the entry into or amending certain material contracts. Vyome and ReShape are required to conduct business in the ordinary course consistent with past practice. The restrictive covenants, which are subject to various specific exceptions, may prevent Vyome or ReShape from pursuing attractive business opportunities that may arise prior to the consummation of the Merger. Although Vyome and ReShape may be able to pursue such activities with the other company's consent, the other company may not be willing to provide its consent.

ReShape directors and executive officers and Vyome directors and executive officers have interests in the Merger and Asset Sale that may be different from, or in addition to, the interests of ReShape stockholders and Vyome stockholders.

Certain of the directors and executive officers of ReShape and certain of the directors and executive officers of Vyome negotiated the terms of the Merger Agreement and these individuals have interests in the Merger that may be different from, or in addition to, those of ReShape stockholders and Vyome stockholders, respectively. These interests include, but are not limited to, the continued service of certain of these Vyome individuals as directors and executive officers of the Combined Company, and one ReShape individual continuing to serve as a director of the Combined Company, after the date of the consummation of the Merger, certain other compensation arrangements with the ReShape and Vyome directors and executive officers, and provisions in the Merger Agreement regarding continued indemnification of and advancement

of expenses of the directors and executive officers of ReShape. ReShape stockholders should be aware of these interests when they consider their respective Boards of Directors' recommendations that they vote in favor of the Merger-related proposals.

With respect to the Asset Sale, certain of the executive officers of ReShape may become employees or consultants to Biorad after the closing of the Asset Sale, though no offers for such positions have been made and no terms of such positions have been discussed or negotiated.

The members of the ReShape Board of Directors (the "Board") were aware of and considered these interests relating to ReShape, among other matters, in evaluating the Merger Agreement and the Merger, and in recommending that ReShape stockholders approve proposals to be voted upon at the ReShape Special Meeting in connection with the Merger.

The members of the Vyome Board were aware of and considered these interests relating to Vyome, among other matters, in evaluating the Merger Agreement and the Merger, and in recommending that Vyome stockholders approve the Merger Agreement and the Merger.

Following the consummation of the Merger, the composition of the board of directors and management of the Combined Company will be comprised of six directors to be nominated by Vyome and its current stockholders and one current ReShape director and ReShape's current stockholders will not have a majority ownership and voting interest in the Combined Company. The Combined Company will focus on Vyome's business of advancing the development of its immuno-inflammatory assets and on identifying additional opportunities between the world-class Indian innovation corridor and the U.S. market.

Pursuant to the Merger Agreement, following the consummation of the Merger, the board of directors of the Combined Company will consist of six directors designated by Vyome and one director designated by ReShape and the executive management of the Combined Company will consist of Vyome's executive officers. No current ReShape officers or employees are expected to continue with the Combined Company.

The Combined Company will focus on Vyome's business of advancing the development of its immuno-inflammatory assets and on identifying additional opportunities between the world-class Indian innovation corridor and the U.S. market. In addition, immediately following completion of the Merger and the issuance of the ReShape Shares to the Vyome stockholders at the Effective Time, ReShape's current stockholders in the aggregate will not have a majority ownership and voting interest in the Combined Company, which will result in ReShape stockholders having less influence on the Combined Company's management and policies. As a result, current ReShape stockholders will have less influence on the Combined Company's management and policies than they currently have.

The opinion of ReShape's financial advisor does not reflect changes in circumstances that may have occurred or that may occur between the signing of the Merger Agreement and the consummation of the Merger.

The opinion rendered to the Board by Maxim Group LLC was provided in connection with, and at the time of, the Board's evaluation of the Merger. Maxim is also acting as the placement agent in this offering (see "Plan of Distribution" herein for more details). The opinion was based on the financial analysis performed, which considered market and other conditions then in effect, and financial forecasts and other information made available to Maxim, as of the date of its opinion, which may have changed, or may change, after the date of the opinion. The Board has not obtained an updated opinion from its financial advisor as of the date of this prospectus or as of any other date, nor does it expect to receive an updated, revised or reaffirmed opinion prior to the consummation of the Merger. Changes in the operations and prospects of ReShape or Vyome, general market and economic conditions and other factors that may be beyond the control of ReShape or Vyome, and which changes were not taken into account by ReShape's financial advisor in rendering its opinion, may significantly alter the value of ReShape or Vyome or the price of ReShape Shares by the time the Merger is consummated. The opinion does not speak as of the time the Merger will be consummated or as of any date other than the date of such opinion. Because there are no plans for ReShape's financial advisor to update their opinion, the opinion does not address the fairness of the Exchange Ratio or the Merger Consideration, as applicable, from a financial point of view, at any time other than the time such opinion was issued.

Failure to consummate the Merger could negatively impact respective future operations and financial results of ReShape and Vyome and the future stock price of ReShape.

If the Merger is not consummated for any reason, ReShape and Vyome may be subjected to a number of material risks, including the following:

- a decline in the market price of the shares of our common stock to the extent that the current market price reflect a market assumption that the Merger will be consummated and will be beneficial to the value of ReShape after the closing date of the Merger;
- having to pay certain costs related to the proposed Merger, such as legal, accounting, financial advisory, printing and mailing fees, which must be paid regardless of whether the Merger is consummated;
- addressing the consequences of operational decisions made since the signing of the Merger Agreement, including because of restrictions on ReShape's or Vyome's operations imposed by the terms of the Merger Agreement and decisions to delay or defer capital expenditures;
- returning the focus of management and personnel to operating ReShape or Vyome, as applicable, on a standalone basis, without any of the benefits expected to have been provided by the consummation of the Merger or, in the case of ReShape, the Asset Sale;
- negative reactions from their respective stockholders, suppliers, employees, and the medical community;
- Vyome's product development plans may get slowed down or discontinued; and
- Vyome and its subsidiary (Vyome India) may lose employees and consultants.

In addition to the above risks, ReShape and Vyome may be required, under certain circumstances, to pay to the other party a termination fee of $1.0 million, which may materially adversely affect such party's financial condition. The business of ReShape or Vyome may be adversely impacted by the failure to pursue other beneficial opportunities due to the focus of ReShape and Vyome management on the Merger. A failure to consummate the Merger may also result in negative publicity, reputational harm, litigation against ReShape or Vyome or their respective directors and officers, and a negative impression of the companies in the financial markets.

If the Merger is not consummated, we cannot assure the Vyome stockholders or the ReShape stockholders that these risks will not materialize and will not materially adversely affect the business, financial results and stock price of the respective companies. Because each of the Merger and the Asset Sale are conditioned upon the other transaction being consummated, neither transaction may be completed if the proposals required for the consummation of both transactions are not approved.

The Merger may disrupt attention of ReShape management and Vyome management from ongoing business operations.

Each of ReShape and Vyome has expended, and expects to continue to expend, significant management resources to consummate the Merger. The attention of each company's management may be diverted away from the day-to-day operations of the businesses of ReShape and Vyome, respectively, including implementing initiatives to improve performance, execution of existing business plans and pursuing other beneficial opportunities, in an effort to consummate the Merger. This diversion of management resources could disrupt ReShape's or Vyome's operations and may have an adverse effect on the respective businesses, financial conditions, results of operations and cash flows of the two companies or the Combined Company after the closing date of the Merger.

The market price for ReShape Shares following completion of the Merger will continue to fluctuate and may be affected by factors different from those that historically have affected ReShape Shares.

Following the completion of the Merger, Vyome stockholders and ReShape stockholders will be stockholders in the Combined Company. ReShape's business differs in important respects from that of Vyome and the Combined Company's business will differ from that of ReShape prior to the completion of

the Merger. Accordingly, the results of operations of the Combined Company and the market price of ReShape Shares after the completion of the Merger may be affected by factors different from those currently affecting the independent results of operations of each of Vyome and ReShape.

Legal proceedings in connection with the Merger, the outcomes of which are uncertain, could delay or prevent the completion of the Merger.

In connection with transactions like the proposed Merger it is not uncommon for lawsuits to be filed against the parties and/or their respective directors and officers alleging, among other things, that the proxy statement/prospectus provided to shareholders contains false and misleading statements and/or omits material information concerning the transaction. To date, ReShape has received five letters on behalf of purported shareholders of the company demanding that ReShape issue certain corrective disclosures in the Form S-4 related to the Merger. Although no lawsuits have yet been filed in connection with the Merger, it is possible that such actions may arise and, if they do arise, to seek, among other things, injunctive relief and an award of attorneys' fees and expenses. Defending such lawsuits could require ReShape and Vyome to incur significant costs and draw the attention of ReShape's and Vyome's management teams away from the consummation of the Merger and the management of their respective businesses. Further, the defense or settlement of any lawsuit or claim that remains unresolved at the time the Merger is consummated may adversely affect the Combined Company's business, financial condition, results of operations and cash flows. Such legal proceedings could delay or prevent the Merger from being consummated within the expected timeframe.

Risks Related to the Business of the Combined Company After the Merger

Combining the two companies may be more difficult, costly or time consuming than expected, and the Combined Company may not realize all of the anticipated benefits of the Merger.

ReShape and Vyome have operated and, until the consummation of the Merger, will continue to operate, independently. The Combined Company may not be able to successfully achieve the anticipated benefits of the Merger at all or they may take longer to realize than expected. The difficulties of operating the Combined Company may include, among others:

- the diversion of management attention to integration matters;
- difficulties in integrating functions, personnel and systems;
- declines in results of operations, financial condition or cash flows;
- a decline in the market price of ReShape Shares;
- contingent liabilities that are larger than expected;
- potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the Merger;
- disruption of existing relationships with patients, doctors, business partners, and other constituencies; and
- the disruption of, or the loss of momentum in, ongoing research and development, including ongoing clinical trials.

Many of these factors are outside the control of ReShape and Vyome, and any one of them could result in increased costs, decreased expected revenues and diversion of management time and energy, which could materially impact the business, financial condition, results of operations and cash flows of the Combined Company. These factors could cause dilution to the earnings per share of the Combined Company, decrease or delay the expected benefits of the Merger and negatively impact the price of ReShape Shares. As a result, it cannot be assured that the Combined Company will realize the full benefits anticipated from the Merger within the anticipated time frames, or at all.

In addition, following the Merger, ReShape will become responsible for Vyome's liabilities and obligations, including with respect to legal, financial, regulatory, and compliance matters. These obligations

will result in additional cost and investment by ReShape and, if ReShape has underestimated the amount of these costs and investments or if ReShape fails to satisfy any such obligations, ReShape and Vyome may not realize the anticipated benefits of the Merger. Further, it is possible that there may be unknown, contingent or other liabilities or problems that may arise in the future, the existence and/or magnitude of which ReShape and Vyome was previously unaware. Any such liabilities or problems could have an adverse effect on the Combined Company's business, financial condition, results of operations or cash flows.

Further, following completion of the Merger, the Combined Company will be susceptible to many of the risks described herein and risks related to Vyome's business. To the extent any of the events in the risks occur, those events could cause the potential benefits of the Merger not to be realized and the market price of the Combined Company's common stock to decline.

ReShape and Vyome will incur substantial direct and indirect costs as a result of the Merger and the Combined Company will incur substantial direct and indirect costs following the Merger.

ReShape and Vyome will incur substantial expenses in connection with and as a result of consummating the Merger, and over a period of time following the consummation of the Merger, ReShape also expects to incur substantial expenses as a Combined Company. A portion of the transaction costs related to the Merger will be incurred regardless of whether the Merger is consummated. While ReShape and Vyome have assumed that a certain level of transaction expenses will be incurred, factors beyond ReShape's and Vyome control could affect the total amount or the timing of these expenses. These expenses could adversely affect the financial condition, results of operations and cash flows of the Combined Company following the consummation of the Merger.

Both ReShape and Vyome have operated with a loss and negative cash flows for the entirety of their existence and it is expected the Combined Company will have to raise significant capital in the future that could be dilutive to stockholders of the Combined Company.

Both ReShape and Vyome have operated with a loss and negative cash flows for the entirety of their existence. The Combined Company may not be able to raise capital to continue operations in the future which could result in bankruptcy or liquidation of the Combined Company. Adequate funding may not be available to the Combined Company on acceptable terms, or at all.

If the perceived benefits of the Merger do not meet the expectations of investors or securities analysts, the market price of ReShape's securities or, following the Merger, the Combined Company's securities, may decline.

If the perceived benefits of the Merger do not meet the expectations of investors or securities analysists, the market price of ReShape's securities prior to the closing of the Merger may decline. The market value of ReShape's securities at the time of the Merger may vary significantly from their prices on the date of the Merger Agreement was executed, the date of this prospectus, or the date of the ReShape Special Meeting.

In addition, following the Merger, fluctuations in the price of the Combined Company's securities could contribute to the loss of all or part of a shareholder's investment. Prior to the Merger, there has not been a public market for Vyome common stock. Accordingly, the valuation ascribed to the Combined Company in the Merger may not be indicative of the price that will prevail in the trading market following the Merger. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. If an active market for the Combined Company's securities develops and continues, the market price of its common stock may fluctuate significantly in response to numerous factors, some of which are beyond the Combined Company's control, such as:

- The Combined Company's ability to commercialize Vyome's assets or their corresponding product candidates, if approved;
- the status and cost of the Combined Company's marketing commitments for Vyome's assets and their product candidates;

- announcements regarding results of any clinical trials relating to the Combined Company's product candidates;
- unanticipated serious safety concerns related to the use of Vyome's assets or any of the Combined Company's product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to Vyome's assets or the Combined Company's product candidates, including but not limited to clinical trial requirements for approvals;
- violation of or non-compliance with applicable laws and regulations (including any laws relating to taxation) in the countries of operation of the Combined Company and its subsidiaries (including India and the U.S.);
- legal disputes (such as infringements, non-allowances, etc.) or other developments relating to proprietary rights, including patents, litigation matters and the Combined Company's ability to obtain patent protection for Vyome's assets or the product candidates, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or shareholder litigation;
- The Combined Company's decision to initiate a clinical trial, not initiate a clinical trial or to terminate an existing clinical trial;
- The Combined Company's dependence on third parties;
- reduction in revenues received by Vyome India going forward on account of reduced business from its existing partnerships with third-parties;
- announcements of the introduction of new products by the Combined Company's competitors;
- market conditions and trends in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results or intellectual property rights of others;
- future issuances of common stock or other securities;
- the recruitment or departure of key personnel;
- failure to meet or exceed any financial guidance or expectations regarding product development milestones that the Combined Company may provide to the public;
- actual or anticipated variations in quarterly operating results;
- The Combined Company's failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to the Combined Company's operating performance or the operating performance of its competitors, including changes in market valuations of similar companies;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by the Combined Company's or its competitors;
- changes in financial estimates by the Combined Company or by any securities analysts who might cover its shares;
- fluctuation of the market values of any of the Combined Company's potential strategic investments;
- issuances of debt or equity securities;
- compliance with the Combined Company's contractual obligations
- sales of shares of common stock of the Combined Company by the Combined Company or its shareholders in the future;
- trading volume of shares of common stock of the Combined Company;
- ineffectiveness of the Combined Company's internal controls;

- publication of research reports about the Combined Company or its industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- general political and economic conditions;
- effects of natural or man-made catastrophic events;
- effects of public health crises, pandemics and epidemics, such as the COVID-19 pandemic or other similar outbreaks; and
- other events or factors, many of which are beyond the Combined Company's control.

Further, the equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of shares of common stock of the Combined Company, which could cause a decline in the value of its common stock. Price volatility of shares of common stock of the Combined Company might worsen if the trading volume of its common stock is low. In the past, shareholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' shares. Such litigation, if instituted against the Combined Company, could cause it to incur substantial costs and divert management's attention and resources from its business. The realization of any of the above risks or any of a broad range of other risks, including those described in these "*Risk Factors*", could have a dramatic and material adverse impact on the market price of shares of common stock of the Combined Company.

You may not have the same benefits as an investor in an underwritten public offering.

The Combined Company will become a publicly listed company upon the completion of the Merger. The Merger and the transactions related thereto are not an underwritten initial public offering of shares of common stock of the Combined Company or Vyome's securities and differ from an underwritten initial public offering in several significant ways, which include, but are not limited to, the following factors.

Like other Mergers and spin-offs which are an underwritten initial public offering, in connection with the Merger, you will not receive the benefits of the diligence performed by underwriters in an underwritten public offering. Investors in an underwritten public offering may benefit from the role of the underwriters in such an offering. In an underwritten public offering, an issuer initially sells its securities to the public market via one or more underwriters, who distribute or resell such securities to the public. Underwriters have liability under the U.S. securities laws for material misstatements or omissions in a registration statement pursuant to which an issuer sells securities. Because the underwriters have a "due diligence" defense to any such liability by, among other things, conducting a reasonable investigation, the underwriters and their counsel conduct a due diligence investigation of the issuer. Due diligence entails engaging legal, financial and/or other experts to perform an investigation as to the accuracy and completeness of an issuer's disclosure regarding, among other things, its business and financial results. Auditors of the issuer will also deliver a "comfort" letter with respect to the financial information contained in the registration statement. In making their investment decision, investors have the benefit of such diligence in underwritten public offerings. In contrast, Vyome and ReShape have engaged financial advisors (rather than an underwriter) in connection with the Merger. The role of a financial advisor differs from that of an underwriter. For example, financial advisors do not act as intermediaries in the sale of securities.

In addition, because there are no underwriters engaged in connection with the Merger, prior to the opening of trading on Nasdaq on the trading day immediately following the closing of the Merger, there will be no book building process and no price at which underwriters initially sold shares to the public to help inform efficient and sufficient price discovery with respect to the initial post-closing trades on Nasdaq. Therefore, buy and sell orders submitted prior to and at the opening of initial post-closing trading of shares of common stock of the Combined Company on Nasdaq will not have the benefit of being informed by a published price range or a price at which the underwriters initially sold shares to the public, as would be the case in an underwritten initial public offering. There will be no underwriters assuming risk in connection with an initial resale of shares of common stock of the Combined Company or helping to stabilize, maintain or affect the public price of such shares following the closing of the Merger. Moreover, we will not engage in, and have not and will not, directly or indirectly, request the financial advisors to engage in, any special selling efforts or stabilization or price support activities in connection with such shares that will be outstanding

immediately following the closing of the Merger. All of these differences from an underwritten public offering of shares of common stock of the Combined Company could result in a more volatile price for shares of common stock of the Combined Company.

Further, we will not conduct a traditional "roadshow" with underwriters prior to the opening of initial post-closing trading of shares of common stock of the Combined Company on Nasdaq. There can be no guarantee that any information disclosed or filed with the SEC will have the same impact on investor education as a traditional "roadshow" conducted in connection with an underwritten initial public offering. As a result, there may not be efficient or sufficient price discovery with respect to shares of common stock of the Combined Company or sufficient demand among potential investors immediately after the closing of the merger, which could result in a more volatile price for shares of common stock of the Combined Company.

Such differences from an underwritten public offering may present material risks to unaffiliated investors that would not exist if Vyome became a publicly listed company through an underwritten initial public offering instead of upon completion of the Merger.

The Combined Company does not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the capital appreciation, if any, of shares of common stock of the Combined Company.

Vyome has not paid cash dividends on its common stock and the Combined Company does not anticipate paying cash dividends on its common stock in the foreseeable future. The payment of dividends on capital shares of the Combined Company will depend on its earnings, financial condition and other business and economic factors affecting the Combined Company at such time as its board of directors may consider relevant. Since the Combined Company does not intend to pay dividends, a shareholder's ability to receive a return on such shareholder's investment will depend on any future appreciation in the market value of its common stock. There is no guarantee that shares of common stock of the Combined Company will appreciate or even maintain the price at which its shareholders have purchased it.

An active trading market for the Combined Company's common stock may not develop and its stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for Vyome's common stock. An active trading market for the Combined Company's shares of common stock may never develop or be sustained. If an active market for its common stock does not develop or is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

Future sales of a substantial number of shares of common stock of the Combined Company may cause the price of its common stock to decline.

If the Combined Company's existing shareholders sell, or indicate an intention to sell, substantial amounts of the shares of common stock of the Combined Company after the closing of the Merger, the trading price of the shares of common stock of the Combined Company could decline and it could impair the Combined Company's ability to raise capital through the sale of additional equity securities. Certain Vyome shareholders are subject to lock-up provisions that restrict their ability to transfer shares of common stock of the Combined Company or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any security convertible into or exercisable or exchanged for the Combined Company until 360 days from the date of closing of the Merger, provided that 20% of the shares subject to the lock-up will be released from the restrictions in the lock-up agreement on the 91st day after the closing and the remainder will be released from the restrictions in equal increments every 30 days thereafter.

You may experience future dilution as a result of future equity offerings by the Combined Company.

In order to raise additional capital for general corporate purposes, in the future the Combined Company may offer additional shares of its common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could have rights superior to existing

stockholders. The price per share at which the Combined Company sells additional shares of its common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings.

Post consummation of the Merger, the Combined Company may have outstanding warrants, which may cause dilution to its stockholders, have a material adverse impact on the market price of its common stock and make it more difficult for it to raise funds through future equity offerings.

Under the terms of the Merger Agreement, as a condition to consummation of the Merger Agreement, all outstanding Warrants to purchase ReShape Shares, including the Warrants and Pre-funded Warrants offered in this offering ("ReShape Warrants"), except for a number of ReShape Warrants exercisable for ReShape Shares representing not more than 2.75% of the fully diluted ReShape Shares as of the date of the Merger Agreement, shall have been exercised in accordance with their terms in exchange for ReShape Shares or shall have been otherwise settled on terms agreed upon between ReShape and the holder thereof such that the ReShape Warrants would be canceled and terminated prior to the Effective Time. Accordingly, even if the aforementioned condition is satisfied by ReShape to the satisfaction of Vyome, ReShape Warrants up to 2.75% of the fully diluted ReShape Shares may not be exercised prior to the consummation of the Merger. These outstanding ReShape Warrants would give the holders a right to exercise in exchange for receiving shares of common stock of the Combined Company. The issuance of such shares of common stock upon the exercise of warrants by the Combined Company would dilute the percentage ownership interest of stockholders, might dilute the book value per share of the Combined Company's common stock and would increase the number of its publicly traded shares, which could depress the market price of its common stock.

In addition to the dilutive effects described above, the perceived risk of dilution as a result of the significant number of outstanding warrants may cause common stockholders of the Combined Company to be more inclined to sell their shares, which would contribute to a downward movement in the price of its common stock. Moreover, the perceived risk of dilution and the resulting downward pressure on the Combined Company's common stock price could encourage investors to engage in short sales of its common stock, which could further contribute to price declines. The fact that the Combined Company's stockholders and warrant holders can sell substantial amounts of common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for it to raise additional funds through the sale of equity or equity-related securities in the future at a time and price that the Combined Company deems reasonable or appropriate, or at all.

The Combined Company's operating results may fluctuate significantly.

The Combined Company expects its operating results to be subject to quarterly, and possibly annual, fluctuations. The Combined Company net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to the Combined Company development programs;
- the addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which the Combined Company may become involved;
- regulatory developments affecting Vyome's assets or the Combined Company's product candidates, regulatory approvals of its product candidates, and the level of underlying demand for such products and purchasing patterns; and
- The Combined Company's execution of any collaborative, licensing or similar arrangements, and the timing of payments The Combined Company may make or receive under these arrangements.

If the Combined Company's quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of its common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in the Combined Company's operating results may, in turn, cause the price of its common stock to fluctuate substantially.

If securities or industry analysts do not publish research or reports about the Combined Company's business, or if they issue an adverse opinion regarding its share, its share price and trading volume could decline.

The trading market for shares of common stock of the Combined Company will be influenced by the research and reports that industry or securities analysts publish about the Combined Company or its business. If no or few securities or industry analysts commence coverage of the Combined Company, the trading price for its shares would be negatively impacted. In the event the Combined Company obtains securities or industry analyst coverage, if any of the analysts who cover it issues an adverse opinion regarding the Combined Company, its business model, its intellectual property or its share performance, or if its clinical trials and operating results fail to meet the expectations of analysts, its share price would likely decline. If one or more of these analysts cease coverage of the Combined Company or fail to publish reports on it regularly, the Combined Company could lose visibility in the financial markets, which in turn could cause its share price or trading volume to decline.

Raising additional capital may cause dilution to the Combined Company's existing shareholders, restrict its operations or require it to relinquish rights to Vyome's assets or its product candidates.

The Combined Company will likely issue additional equity securities to fund future expansion and pursuant to equity incentive or employee benefit plans. It may also issue additional equity for other purposes. These securities may have the same rights as shares of common stock of the Combined Company or, alternatively, may have dividend, liquidation or other preferences to shares of common stock of the Combined Company, including shares of common stock of the Combined Company issued in connection with the Merger. The issuance of additional equity securities will dilute the holdings of existing shareholders and may reduce the share price of shares of common stock of the Combined Company.

In accordance with the Merger Agreement, each Vyome stock option and restricted stock share outstanding immediately prior to the Effective Time, whether vested or unvested shall be converted into and exchangeable for stock options or restricted stock units, respectively, to receive a number of ReShape Shares equal to the number of shares of Vyome common stock issuable upon exercise of such Vyome stock options or restricted stock units multiplied by the Exchange Ratio with, in the case of stock options, an exercise price equal to the exercise price of such Vyome stock option divided by the Exchange Ratio and otherwise in accordance with the terms and conditions of such Vyome stock option. In addition, post consummation of the Merger, if the board of directors of the Combined Company elects to institute new equity incentive plans or increase the number of shares available for future grant under its existing equity incentive plan, stockholders may experience additional dilution, which could cause the Combined Company's stock price to fall.

Pursuant to certain Registration Rights Agreements entered into in connection with the Merger, certain shareholders of Vyome can each demand that the Combined Company register their registrable securities under certain circumstances and will each also have piggyback registration rights for these securities. In addition, following the closing of the Merger, the Combined Company will be required to file and maintain an effective registration statement under the Securities Act covering such securities and certain of its other securities. The registration of these securities will permit the public sale of such securities, subject to certain contractual restrictions imposed by the Lock-Up Agreements with certain Vyome stockholders and the Merger Agreement. The presence of these additional shares of common stock trading in the public market may have an adverse effect on the market price of the Combined Company's securities.

If the Combined Company raises additional funds through collaboration, licensing or other similar arrangements, it may have to relinquish valuable rights to Vyome's assets or any product candidates, or grant licenses on terms unfavorable to the Combined Company. If adequate funds are not available, the Combined Company's ability to achieve profitability or to respond to competitive pressures would be significantly limited and the Combined Company may be required to delay, significantly curtail or eliminate the development of Vyome's assets.

The Combined Company's principal shareholders, directors and executive officers will own a significant percentage of its capital shares, and also have significant influence over the Combined Company's management.

Following the closing of the Merger, the Combined Company's directors, executive officers, holders of 5% or more of the Combined Company's capital shares and their respective affiliates are expected to

beneficially own, in the aggregate, approximately 62.92% of the Combined Company's outstanding voting shares. This concentration of voting power may make it less likely that any other holder of shares of common stock of the Combined Company will be able to affect the way the Combined Company is managed and could delay or prevent an acquisition of the Combined Company on terms that other shareholders may desire. This could prevent transactions in which shareholders might otherwise recover a premium for their shares over current market prices. See above for additional information regarding Vyome's influence and control in the Combined Company.

Further, under the Merger Agreement, KKG Enterprises, LLC (an entity under the control of Krishna K. Gupta, who shall be the Chairman of the Combined Company) and Shiladitya Sengupta, each have a right to appoint 2 (two) directors on the board of directors of the Combined Company, which shall in total comprise of 7 (seven) members. Accordingly, the aforesaid individuals will have control over the appointment of a majority of directors on the board of the Combined Company, and directly or indirectly be able to affect the decisions of the board, and, through their recommendations, of the shareholders of the Combined Company.

If the Combined Company's estimates or judgments relating to its critical accounting policies are based on assumptions that change or prove to be incorrect, its operating results could fall below its publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of its common stock.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the Combined Company's financial statements and accompanying notes. The Combined Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If the Combined Company's assumptions change or if actual circumstances differ from its assumptions, its operating results may be adversely affected and could fall below its publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of shares of common stock of the Combined Company.

The Combined Company's ability to use net operating losses ("NOL") carryforwards may be limited.

The Combined Company's ability to use its federal and state NOL carryforwards to offset potential future taxable income may be dependent upon its generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether it will generate sufficient taxable income to use all of our NOL carryforwards. As of December 31, 2023, Vyome had U.S. NOL carryforwards of approximately $400,000 that will expire through 2035 and $15,300,000 that have no expiration date. As of December 31, 2023, ReShape had U.S. NOL carryforwards of $218.9 million, state NOL carryforwards of $348.7 million and foreign NOL carryforwards of $0.2 million. Of ReShape's total U.S. federal net operating loss carryforwards at December 31, 2023, losses generated beginning in 2018 will carryover indefinitely.

The Combined Company's ability to utilize its net operating loss carryforwards, tax credits, and built-in items of deduction, including capitalized start-up costs and research and development costs, has been, and may continue to be substantially limited due to ownership changes. These ownership changes limit the amount of net operating loss carryforwards, credits and built-in items of deduction that can be utilized annually to offset future taxable income. In general, an ownership change, as defined in IRC Section 382, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups.

Adverse developments affecting the financial services industry could adversely affect the Combined Company's current and projected business operations and its financial condition and results of operations.

If financial institutions in which the Combined Company holds funds for working capital and operating expenses were to fail, there can be no assurance that such governmental agencies would take action to protect the Combined Company's uninsured deposits in a similar manner.

If a financial institution in which the Combined Company holds such funds fails or is subject to significant adverse conditions in the financial or credit markets, it could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact the Combined Company's short-term liquidity and ability to meet its operating expense obligations.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for the Combined Company to acquire financing on acceptable terms or at all. Any decline in available funding or access to the Combined Company's cash and liquidity resources could, among other risks, adversely impact its ability to meet its operating expenses, financial obligations or fulfill our other obligations, result in breaches of its financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on the Combined Company's liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, a vendor on which the Combined Company is reliant could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution.

Any critical vendor bankruptcy or insolvency, or any breach or default by a critical vendor, or the loss of any significant vendor relationships, may have a material adverse impact on the Combined Company's business.

If the Combined Company is unable to develop and maintain an effective system of internal control over financial reporting, it may not be able to accurately report its financial results in a timely manner, which may adversely affect investor confidence in the Combined Company and materially and adversely affect its business and operating results.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Combined Company's annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

Effective internal controls are necessary to provide reliable financial reports and prevent fraud. While the Combined Company intends to have systems and processes in place to identify and if necessary, continues to evaluate steps to remediate the material weakness. These remediation measures may be time consuming and costly and there is no assurance that these initiatives will ultimately have the intended effects.

If the Combined Company identifies any new material weaknesses in the future, any such newly identified material weakness could limit its ability to prevent or detect a misstatement of its accounts or disclosures that could result in a material misstatement of its annual or interim financial statements. In such case, the Combined Company may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in the Combined Company's financial reporting and its share price may decline as a result.

The Combined Company will incur increased costs as a result of operating as a public company, and its management will devote substantial time to related compliance initiatives.

As a public company, the Combined Company will incur significant legal, accounting and other expenses that Vyome did not incur as a private company. The Combined Company will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), as well as rules and regulations adopted, and to be adopted, by the SEC and Nasdaq. The Combined Company's management and other personnel will need to devote a substantial amount of time to these

compliance initiatives. Moreover, the Combined Company expects these rules and regulations to substantially increase its legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase its operating expenses. For example, the Combined Company expects these rules and regulations to make it more difficult and more expensive for the Combined Company to obtain directors' and officers' liability insurance and the Combined Company may be required to incur substantial costs to maintain sufficient coverage. the Combined Company cannot predict or estimate the amount or timing of additional costs it may incur to respond to these requirements. The impact of these requirements could also make it more difficult for the Combined Company to attract and retain qualified persons to serve on its board, its board committees or as executive officers. Advocacy efforts by shareholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

As a public company, the Combined Company will be required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, the Combined Company will be required to make a formal assessment of the effectiveness of its internal control over financial reporting, and once it ceases to be an emerging growth company, the Combined Company will be required to include an attestation report on internal control over financial reporting issued by its independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, the Combined Company will be engaging in a process to document and evaluate its internal control over financial reporting, which is both costly and challenging. In this regard, the Combined Company will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of its internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess the Combined Company's internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, the Combined Company's management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. These reporting and other obligations place significant demands on the Combined company's management and administrative and operational resources, including accounting resources.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. The Combined Company intends to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of its management's time and attention from revenue-generating activities to compliance activities. If the Combined Company's efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against the Combined Company and there could be a material adverse effect on the Combined Company's business, financial condition and results of operations.

Certain of the Combined Company's proposed directors and executive officers also work with other companies and organizations and such other positions may create conflicts of interest in the future.

Some of the Combined Company's officers and directors will serve only part-time and are subject to conflicts of interest. Each of such officers and directors will be devoting part of their working time to other endeavors, including consulting relationships with other entities, and may have responsibilities to these other entities. Such conflicts may also include deciding how much time to devote to the Combined Company's affairs. Because of these relationships, our officers and directors may be subject to conflicts of interest.

For example, Venkat Nelabhotla, Vyome's Chief Executive Officer and who will be the Chief Executive Officer of the Combined Company, will be devoting approximately 40 hours per week to the Combined Company's business, but as much time as necessary. Mr. Nelabhotla also works part-time in a consulting/ advisory capacity for Pulse Pharmaceuticals Private Limited and Newvojax Health and Wellness Private Limited for approximately 15 hours per week. Mr. Shiladitya Sengupta, one of the co-founders and directors of Vyome, will also be a director on the board of the Combined Company. He works full-time as an Associate Professor of Medicine at the Brigham and Women's Hospital and Harvard Medical School and will be dedicating his time to the Combined Company on a limited, as-needed basis. Mr. Sengupta also works in a consulting capacity for Alyssum Therapeutics Inc, CBCC, Invictus Oncology Pvt Ltd, India Innovation Research Center for approximately 4 hours per week. Further, Robert Dickey, Vyome's Chief Financial Officer and who will be the Chief Financial Officer of the Combined Company, will be working with the Combined Company for 50% of his available time or a minimum of 80 hours per month. While Vyome has not, and Vyome believes that the Combined Company will not, encounter any issue as a result of such additional roles/ responsibilities, the duties to such businesses/ organizations may compete for such persons' full attention to the Combined Company's business; accordingly, they may have conflicts of interest in allocating time between the separate business activities.

General economic and political conditions could have a material adverse effect on the Combined Company.

External factors can affect our financial condition. Such external factors include general domestic and global economic conditions, such as interest rates, tax law including tax rate changes, and factors affecting global economic stability, and the political environment regarding healthcare in general. We cannot predict to what extent the global economic conditions may negatively impact the Combined Company's business. For example, negative conditions in the credit and capital markets could impair our ability to access the financial markets for working capital and could negatively impact our ability to borrow.

If the Combined Company's competitors are able to develop and market products that are safer or more effective than the Combined Company's products, its commercial opportunities will be reduced or eliminated.

The health care industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The immune-inflammatory disease market in which the Combined Company intends to operate has grown significantly in recent years and is expected to continue to expand as technology continues to evolve and awareness of the need to treat immune-inflammatory diseases grows. The Combined Company will face potential competition from several big pharma and mid/small size biotech and pharma companies. Many of the Combined Company's competitors will likely have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they pursue competing solutions through collaborative arrangements with large and established companies. The Combined Company's competitors may develop and patent processes or products earlier than it, obtain regulatory approvals for competing products more rapidly than the Combined Company is able to and develop more effective, safer and less expensive products or technologies that would render its products non-competitive or obsolete.

The Combined Company may face significant uncertainty in the industry due to government healthcare reform.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act, as amended, (the "Affordable Care Act") as well as any future healthcare reform legislation, may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits.

Congress regularly considers legislation to replace or repeal elements or all of the Affordable Care Act. At this time, it is not clear whether the Affordable Care Act will be repealed in whole or in part, and, if it is repealed, whether it will be replaced in whole or in part by another plan and what impact those changes will

have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payers are willing to pay. In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce the Combined Company's revenue, increase our costs, or require us to revise the ways in which we conduct business or put it at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future.

The Combined Company may be subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and the Combined Company may become subject to such litigation. If the Combined Company is unable to, or have not fully complied with such laws, it could face substantial penalties.

The Combined Company's operations, directly or indirectly through customers, may be subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

The Combined Company may be unable to predict whether it could be subject to actions under any of these laws, or the impact of such actions. If the Combined Company is found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, it may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of its operations.

Failure to protect the Combined Company's information technology infrastructure against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt its operations and adversely affect its business.

The operation of the Combined Company's business will depends on our information technology systems. It will rely on its information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Its information technology systems may be

vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data corruption, and cyber-based attacks. Cyber-based attacks can include computer viruses, computer denial-of-service attacks, phishing attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. In addition, federal, state, and international laws and regulations, such as the General Data Protection Regulation adopted by the European Union and European Economic Area countries can expose the Combined Company to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if the Combined Company's information technology security efforts fail.

The Combined Company may in the future become involved in lawsuits, to protect or enforce its intellectual property, which can be expensive and time consuming and could result in the diversion of significant resources.

Adverse proceedings such as litigation or challenges to the validity of our patents can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm its business, whether or not it receive a favorable determination. In addition, in an infringement or other adverse proceeding, a court may decide that the patent the Combined company seeks to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation or proceeding could place one or more of the Combined Company's patents at risk of being invalidated, interpreted narrowly or found unenforceable. Some of its competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against the Combined Company, if it asserts rights against them.

The Combined Company may lose important patents or patent rights if it does not timely pay required patent fees or annuities.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may result in loss of patents or patent rights important to the Combined Company's business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical products.

Many of the Combined Company's competitors may have significant resources and incentives to apply for and obtain intellectual property rights that could limit or prevent its ability to commercialize our current or future products in the United States or abroad.

Many of the Combined Company's competitors who have significant resources and have made substantial investments in competing technologies may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the U.S. or in international markets. The Combined Company's U.S. or foreign patents may be challenged, circumvented by competitors or others or may be found to be invalid, unenforceable or insufficient. In most cases in the United States patent applications are published 18 months after filing the application, or corresponding applications are published in other countries, and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, there can be no certainty that the Combined Company was the first to make the inventions covered by each of its pending patent applications, or that it was the first to file patent applications for such inventions.

If the Combined Company is unable to protect the confidentiality of our proprietary information and know-how, the value of its technology and products could be adversely affected.

In addition to patented technology, the Combined Company may rely on its unpatented proprietary technology, trade secrets, processes and know-how. It would generally seek to protect this information by

confidentiality agreements with employees, consultants, scientific advisors and third parties. These agreements may be breached, and the Combined Company may not have adequate remedies for any such breach. In addition, its trade secrets may otherwise become known or be independently developed by competitors. To the extent that the Combined Company's employees, consultants or contractors use intellectual property owned by others in their work for the Combined Company, disputes may arise as to the rights in related or resulting know-how and inventions.

Intellectual property litigation is a common tactic in the biotech industry to gain competitive advantage. If the Combined Company becomes subject to a lawsuit, it may be required to expend significant financial and other resources and our management's attention may be diverted from its business.

There has been a history of frequent and extensive litigation regarding patent and other intellectual property rights in the biotech industry, and companies in the biotech industry have employed intellectual property litigation to gain a competitive advantage. Accordingly, the Combined Company may become subject to patent infringement claims or litigation in a court of law, or interference proceedings declared by the U.S. Patent and Trademark Office ("USPTO") to determine the priority of inventions or an opposition to a patent grant in a foreign jurisdiction. It may also become subject to claims or litigation seeking payment of royalties based on sales of its product in connection with licensing or similar joint development arrangements with third parties or in connection with claims of patent infringement.

The defense and prosecution of intellectual property suits, USPTO interference proceedings, reexamination proceedings, or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, or opposition proceedings and related legal and administrative proceedings, are both costly and time consuming and could result in substantial uncertainty to us. Litigation or regulatory proceedings may also be necessary to enforce patent or other intellectual property rights of ours or to determine the scope and validity of other parties' proprietary rights. Any litigation, opposition or interference proceedings, with or without merit, may result in substantial expense to us, cause significant strain on the Combined Company's financial resources, divert the attention of its technical and management personnel and harm its reputation. The Combined Company may not have the financial resources to defend its patents from infringement or claims of invalidity. An adverse determination in any litigation could subject us to significant liabilities to third parties, require it to seek licenses from or pay royalties to third parties or prevent it from manufacturing, selling or using our proposed products, any of which could have a material adverse effect on its business and prospects.

As a result of patent infringement claims, or to avoid potential claims, the Combined Company may choose or be required to seek a license from a third-party and be required to pay license fees or royalties, or both. A license may not be available at all or on commercially reasonable terms, and the Combined Company may not be able to redesign its products to avoid infringement. Modification of our products or development of new products could require it to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. Even if the Combined Company were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to cease some aspect of its business operations if, as a result of actual or threatened patent infringement claims, it is unable to enter into licenses on acceptable terms. This could harm our business significantly.

Risks Related to Our Business and Industry

If we are unable to either substantially improve our operating results or obtain additional financing, we may be unable to continue as a going concern.

We currently do not generate revenue sufficient to offset operating costs and anticipate such shortfalls to continue, partially due to the introduction of GLP-1 pharmaceuticals. As of September 30, 2024, we had cash, cash equivalents and restricted cash of $0.74 million and $1.34 million of accounts receivable. Based on our available cash resources, we do not have sufficient cash on hand to fund our current operations for more than 12 months from the date of filing this prospectus. Even if we sell all of the securities in this offering, we still may not have sufficient cash on hand to fund our current operations for more than 12 months from the date of filing this prospectus. This condition raises substantial doubt about our ability to continue as a going concern.

We have recently undertaken a cost reduction plan and reorganization, and may do so again in the future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits therefrom.

In light of recent macroeconomic conditions and the impact of GLP-1 prescriptions for weight loss treatment, we announced a 2024 cost reduction plan and reorganization to promote the long-term sustainability and scalability of ReShape. As part of this plan, we have significantly reduced our workforce. This reduction in force, and any other future reductions, and the attrition that may occur following them, result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. These actions and other additional measures we might take to reduce costs could strain our workforce, divert management attention, yield attrition beyond our intended reduction in force, reduce employee morale, cause us to delay, limit, reduce or eliminate certain development plans or otherwise interfere with our ability to operate and grow our business effectively, each of which could have an adverse impact on our business, operating results and financial condition. We may not complete the current or any cost reduction plan and reorganization on the anticipated timetable, and even if successfully completed, we may not achieve the anticipated cost savings, operating efficiencies or other benefits of such activities.

We may be unable to attract and retain management and other personnel we need to succeed, particularly in light of the 2024 cost reduction plan.

Our success depends on the services of our senior management and other key employees. The loss of the services of one or more of our officers or key employees could hinder our sales and marketing efforts, or delay or prevent the commercialization of our Lap-Band System, Lap-Band 2.0, the Obalon Balloon System, and the development of our DBSN device. Our continued growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities. In light of our 2024 cost reduction plan, we are unlikely to hire additional management or other personnel.

We cannot assure you that we will ever generate substantial revenue or be profitable.

The success of our business will depend on our ability to generate increased sales and control costs, as well as our ability to obtain additional regulatory approvals needed to market new versions of our Lap-Band System, Obalon Balloon System, or regulatory approvals needed to market our DBSN device and any other products we may develop in the future, all of which we may be unable to do. If we are unable to successfully market our Lap-Band System for its indicated use, successfully re-introduce the Obalon Balloon System, or develop and commercialize the DBSN device, we may never become profitable and may have to cease operations as a result.

Previously, we recorded a non-cash indefinite-lived intangible and definite-lived assets impairment loss, which significantly impacted our results of operations, and we may be exposed to additional impairment losses that could be material.

We conduct our annual indefinite-lived intangible assets impairment analysis during the fourth quarter of each year or when circumstances suggest that an indicator for impairment may be present. Previously, we performed a qualitative impairment analysis of the in-process research and development (“IPR&D”). Due to delays in the clinical trials experienced, we revised its expectations of when revenues would commence for the ReShape Vest, thus reducing the projected near-term future net cash flows related to the ReShape Vest. During the quarter ended September 30, 2022, we stopped the clinical trials for the ReShape Vest and closed out the previous trials that occurred, as significant additional clinical work and cost would be required to achieve regulatory approval for the ReShape Vest. In addition, due to continued market decline and projected cash flows the company recorded an impairment of the developed technology related to the Lap-Band and Obalon Balloon System and our tradenames. As such, we determined the carrying value of the long-lived assets were impaired and recognized a non-cash impairment charge of approximately $0.8 million on the

statement of operations as of December 31, 2023 and approximately $18.7 million as of December 31, 2022. In the future, we may have additional impairments requiring us to record an impairment loss related to our remaining finite-lived intangible assets, which could also have a material adverse effect on our results of operations.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as rules subsequently implemented by the SEC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in increased legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. We have incurred and continue to expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. Moreover, if we do not comply with the requirements of Section 404, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

For example, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023, and determined that our internal control over financial reporting was not effective at a reasonable assurance level due to material weaknesses in our internal control over financial reporting. We had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process. We are currently implementing our remediation plan to address the material weaknesses identified above. Such measures include: designing and implementing controls to formalize roles and review responsibilities to align with our team's skills and experience and designing and implementing formalized controls; and designing and implementing formal processes, policies and procedures supporting our financial close process.

We have identified material weaknesses in our internal control over financial reporting and any failure to maintain effective internal control over financial reporting, may have a material and adverse effect on our business, operating results, financial condition and prospects.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023, and determined that our internal control over financial reporting was not effective at a reasonable assurance level due to material weaknesses in our internal control over financial reporting. We had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process. We are currently implementing our remediation plan to address the material weaknesses identified above. Such measures include: designing and implementing controls to formalize roles and review responsibilities to align with our team's skills and experience and designing and implementing formalized controls; and designing and implementing formal processes, policies and procedures supporting our financial close process.

General economic and political conditions could have a material adverse effect on our business.

External factors can affect our financial condition. Such external factors include general domestic and global economic conditions, such as interest rates, tax law including tax rate changes, and factors affecting global economic stability, and the political environment regarding healthcare in general. We cannot predict to what extent the global economic conditions may negatively impact our business. For example, negative

conditions in the credit and capital markets could impair our ability to access the financial markets for working capital and could negatively impact our ability to borrow.

We face significant uncertainty in the industry due to government healthcare reform.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act as well as any future healthcare reform legislation, may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits.

Congress regularly considers legislation to replace or repeal elements or all of the Affordable Care Act. At this time, it is not clear whether the Affordable Care Act will be repealed in whole or in part, and, if it is repealed, whether it will be replaced in whole or in part by another plan and what impact those changes will have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payers are willing to pay. In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future.

We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business.

The operation of our business depends on our information technology systems. We rely on our information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data corruption, and cyber-based attacks. Cyber-based attacks can include computer viruses, computer denial-of-service attacks, phishing attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. In addition, federal, state, and international laws and regulations, such as the General Data Protection Regulation adopted by the European Union and European Economic Area countries can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. In addition, a variety of our software systems are cloud-based data management applications, hosted by third-party service providers whose security and information technology systems are subject to similar risks.

We operate in a highly competitive industry that is subject to rapid change. If our competitors are able to develop and market products that are safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The health care industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The obesity treatment market in which we operate has grown significantly in recent years and is expected to continue to expand as technology continues to evolve and awareness of the need to treat the obesity epidemic grows. Although we are not aware of any competitors in the neuroblocking market, we face potential competition from pharmaceutical and surgical obesity treatments. Many of our competitors in the obesity treatment field have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they pursue competing solutions through collaborative arrangements with large and established companies, such as Allergan, Boston Scientific, LivaNova PLC, Johnson & Johnson, Medtronic or St. Jude Medical. Our competitors may develop and patent processes or products earlier than us, obtain regulatory approvals for competing products more rapidly than we are able to and develop more effective, safer and less expensive products or technologies that would render our products non-competitive or obsolete.

We face external competition from other technologies such as GLP-1's, and alternative medical procedures and we may not be able to compete effectively.

Companies that may not be deemed competitors in the bariatric surgery space may develop technologies, products or services that may impact the use of our products. For example, certain therapeutic treatments, such as drugs used to treat weight loss such as GLP-1's, may enhance patient health. If we do not introduce new products and enhancements in a timely manner, there may be a decrease in the use of certain of our products, in which case our operating results could suffer.

Our ability to use net operating losses ("NOL") carryforwards may be limited.

Our ability to use our federal and state NOL carryforwards to offset potential future taxable income is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether we will generate sufficient taxable income to use all of our NOL carryforwards. As of December 31, 2023, ReShape had U.S. federal net operating loss carryforwards of $218.9 million. Of the total U.S. federal net operating loss carryforwards at December 31, 2023, losses generated beginning in 2018 will carryover indefinitely. ReShape had state net operating loss carryforwards of $348.7 million at December 31, 2023, and had foreign net operating loss carryforwards of $0.2 million at December 31, 2023. Net operating loss carryforwards of ReShape are subject to review and possible adjustment by the taxing authorities. With certain exceptions (e.g. the net operating loss carryforwards), ReShape is no longer subject to U.S. federal, state or local examinations by tax authorities for years prior to 2016. There are no tax examinations currently in progress.

ReShape's ability to utilize its net operating loss carryforwards, tax credits, and built-in items of deduction, including capitalized start-up costs and research and development costs, has been, and may continue to be substantially limited due to ownership changes. These ownership changes limit the amount of net operating loss carryforwards, credits and built-in items of deduction that can be utilized annually to offset future taxable income. In general, an ownership change, as defined in IRC Section 382, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups. Due to the valuation allowance against deferred tax assets at December 31, 2023, the net effect of any further limitation will have no impact on results of operations.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Substantially all of our cash and cash equivalents were held in accounts with Silicon Valley Bank ("SVB") at the time it was closed by state regulators, and the Federal Deposit Insurance Corporation ("FDIC") was appointed receiver for SVB, on March 10, 2023. The FDIC created a successor bridge bank for SVB and all deposits of SVB were transferred to the bridge bank under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

We subsequently moved and hold a portion of our cash and cash equivalents in accounts with Bank of America. The balance held in these accounts exceeds the FDIC standard deposit insurance limit of $250,000. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, a vendor on which we are reliant could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on

existing credit facilities involving a troubled or failed financial institution. Any critical vendor bankruptcy or insolvency, or any breach or default by a critical vendor, or the loss of any significant vendor relationships, may have a material adverse impact on our business.

Risks Associated with Development and Commercialization of ReShape's Lap-Band System, Lap-Band 2.0 System, Obalon Balloon System, and the DBSN Device

Our efforts to increase revenue from our Lap-Band System, Lap-Band 2.0 System, and commercialize our DBSN device and expanded line of bariatric surgical accessories, including ReShape Calibration Tubes, may not succeed or may encounter delays which could significantly harm our ability to generate revenue.

Our ability to generate revenue will depend upon the sales of our Lap-Band System, expanded line of bariatric surgical accessories and successful commercialization of our DBSN device (if approved for sale). Our efforts to commercialize these products may not succeed for a number of reasons, including:

- we may not be able to obtain the regulatory approvals required for our DBSN device;
- we may not be able to produce the Obalon Balloon System cost-effectively;
- if we are able to produce the Obalon Balloon System, we may not be able to re-introduce the system into the marketplace;
- our products may not be accepted in the marketplace by physicians, patients and third-party payers;
- the price of our products, associated costs of the surgical procedure and treatment and the availability of sufficient third-party reimbursement for the system implantation and follow-up procedures;
- appropriate reimbursement and/or coding options may not exist to enable billing for the system implantation and follow-up procedures for our DBSN device;
- coverage policies for bariatric surgeries and procedures, including Lap-Band and balloons may be restricted in the future;
- we may not be able to sell our products at a price that allows us to meet the revenue targets necessary to generate enough revenue for profitability;
- the frequency and severity of any side effects of our products;
- physicians and potential patients may not be aware of the perceived effectiveness and sustainability of the results of our products;
- we, or the investigators of our products, may not be able to have information on the outcome of the trials published in medical journals;
- the availability and perceived advantages and disadvantages of alternative treatments, including pharmaceutical treatments;
- any rapid technological change may make our products obsolete;
- we may not be able to have our products manufactured in commercial quantities or at an acceptable cost;
- we may not have adequate financial or other resources to complete the development and commercialization of our products or to develop sales and marketing capabilities for our products; and
- we may be sued for infringement of intellectual property rights and could be enjoined from manufacturing or selling our products.

Besides requiring physician adoption, market acceptance of our products will depend on successfully communicating the benefits of our products to three additional constituencies involved in deciding whether to treat a particular patient using our products: (1) the potential patients themselves; (2) institutions such as hospitals, where the procedure would be performed and opinion leaders in these institutions; and (3) third-party payers, such as private healthcare insurers and governmental payers, such as Medicare and Medicaid in the United States, which would ultimately bear most of the costs of the various providers and

equipment involved in our Lap-Band System, Obalon Balloon System, and DBSN device (if approved for sale). Marketing to each of these constituencies requires a different marketing approach, and we must convince each of these groups of the efficacy and utility of our products to be successful.

During the year ended December 31, 2023 and 2022, there was minimal revenue for ReShapeCare and ReShape Marketplace. There was no revenue or gross profit recorded for the DBSN device for the year ended December 31, 2023 and 2022 as this product is still in the research stage of development. There was also no revenue recorded for the Obalon line.

If our products, or any other therapy or products that we may develop for other gastrointestinal diseases and disorders that we may develop, do not achieve an adequate level of acceptance by the relevant constituencies, we may not generate significant product revenue and may not become profitable. This estimated timeline could be compressed or extended depending on many factors, including revenue growth from new product introductions, strategic investments not yet foreseen, and other risks and uncertainties due to the general business, economic, regulatory, market and financial conditions. Therefore, the plans cannot be deemed probable of being implemented. As a result, the Company's plans do not alleviate substantial doubt about our ability to continue as a going concern.

We may not be able to obtain required regulatory approvals for our DBSN device in a cost-effective manner or at all, which could adversely affect our business and operating results.

The production and marketing of our DBSN device, and our ongoing research and development, preclinical testing and future potential clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U.S. and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the development, testing, marketing and premarket review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, exporting, labeling and record keeping procedures. We are required to obtain regulatory approval before we can market our DBSN device in the United States and certain foreign countries. The regulatory process will require significant time, effort and expenditures to bring products to market, and it is possible that our DBSN device will not be approved for sale. Even if regulatory approval of our DBSN device is granted, it may not be granted within the timeframe that we expect, which could have an adverse effect on our operating results and financial condition. Even after our DBSN device is approved by the FDA, we may have ongoing responsibilities under FDA regulations, non-compliance of which could result in the subsequent withdrawal of such approvals, or such approvals could be withdrawn due to the occurrence of unforeseen problems following initial approval. We also are subject to medical device reporting regulations that require us to report to the FDA if any of our products causes or contributes to a death or serious injury or if a malfunction were it to occur might cause or contribute to a death or serious injury. Any failure to obtain regulatory approvals on a timely basis or the subsequent withdrawal of such approvals could prevent us from successfully marketing our products, which could adversely affect our business and operating results.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

While we currently do not have any active clinical trials enrolling patients, we may in the future need to rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, ensure compliance by patients with clinical protocols or comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining or maintaining regulatory approvals for our product. Our agreements with clinical investigators and clinical trial sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory

requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, adversely affecting our ability to successfully commercialize our product.

Modifications to the Lap-Band and Lap-Band 2.0 system may require additional approval from regulatory authorities, which may not be obtained or may delay our commercialization efforts.

The FDA and our European Notified Body require medical device companies to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, some of these regulatory authorities can review a company's decision. Any modifications to an approved device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use could require additional clinical studies and separate regulatory applications. Product changes or revisions will require all the regulatory steps and associated risks discussed above possibly including testing, regulatory filings and clinical studies. We may not be able to obtain approval of supplemental regulatory approvals for product modifications, new indications for our product or new products. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our commercialization efforts and future growth.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated product problems, our Lap-Band system could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by our European Notified Body and the FDA and other regulatory bodies. In particular we and our manufacturers and suppliers are required to comply with ISO requirements, Good Manufacturing Practices, which for medical devices is called the Quality System Regulation ("QSR"), and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval. The FDA enforces the QSR through inspections, which may be unannounced, and the CE system enforces its certification through inspections and audits as well. Our quality system has received certification of compliance to the requirements of ISO 13485:2016 and will have to continue to successfully complete such inspections to maintain regulatory approvals for sales outside of the United States. Failure by us or one of our manufacturers or suppliers to comply with statutes and regulations administered by the FDA, CE authorities and other regulatory bodies, or failure to adequately respond to any observations, could result in enforcement actions against us or our manufacturers or suppliers, including, restrictions on our product or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

If any of these actions were to occur it would harm our reputation and cause our product sales to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements. If the FDA or any other regulatory body finds their compliance status to be unsatisfactory, our commercialization efforts could be delayed, which would harm our business and our results of operations.

Additionally, if the FDA determines that our promotional materials, training or other activities constitute promotion of an unapproved use, we could be subject to significant liability, the FDA could request that we cease, correct or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

We are subject to medical device reporting regulations that require us to report to the FDA, national bodies known as Competent Authorities or other governmental authorities in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material

deficiencies or defects in design or manufacturing. A government mandated, or voluntary, recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall would divert managerial and financial resources and could harm our reputation with customers. There can be no assurance that there will not be product recalls in the future or that such recalls would not have a material adverse effect on our business. Once the product is approved and implanted in a large number of patients, infrequently occurring adverse events may appear that were not observed in the clinical trials. This could cause health authorities in countries where the product is available to take regulatory action, including marketing suspension and recall.

For example, on January 18, 2023, we received a letter from the FDA requesting additional information regarding Medical Device Reports submitted in 2021 related adverse events associated with a Lap-Band device and pregnancy. The FDA's letter indicates a concern for an increased risk for Lap-Band complications in pregnant patients and requests that we provide, among other information, any actions planned or implemented which might reduce the likelihood of such events, which we are in the process of responding to. We believe there is robust peer-reviewed published data that supports our belief that concerns raised by the FDA are anomalies and rare occurrences. For example, a June 2022 consensus statement on laparoscopic adjustable gastric band (LAGB) management, which includes the Lap-Band, by the ASMBS found that (i) a tailored approach to LAGB management during pregnancy allows patients and providers to monitor weight gain, nutritional adequacy, and fetal growth for a healthy pregnancy outcome and (ii) evidence supports LAGB placement as safe and well tolerated during pregnancy with close LAGB monitoring. While improbable, if there are additional, or more serious, adverse events for pregnant Lap-Band patients, or if the FDA issues a warning regarding, or restricts the use of, the Lap-Band with pregnant patients, or patients who may become pregnant, our business could be harmed. One of the goals of our direct-to-consumer marketing campaign is to help people understand that the Lap-Band offers unique benefits for a variety of obese patients, including patients who may become pregnant. If there is a perception that the Lap-Band is not safe for pregnant patients, it could harm our reputation and cause our Lap-Band sales to suffer.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to obtain adequate product liability insurance.

Our business exposes us to a risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. The medical device industry has historically been subject to extensive litigation over product liability claims. We have previously reported adverse events associated with the Lap-Band system, including as related to pregnant patients, and may be subject to product liability claims if our products cause, or appear to have caused, an injury. Claims may be made by consumers, healthcare providers, third-party strategic collaborators or others selling our products.

We have product liability insurance, which covers the use of our products in our clinical trials and any commercial sales, in an amount we believe is appropriate. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost and on acceptable terms for an adequate coverage amount, or otherwise to protect against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

We may be subject to product liability claims even if it appears that the claimed injury is due to the actions of others. For example, we rely on the expertise of surgeons and other associated medical personnel to perform the medical procedure to implant and remove our products and to perform the related therapy. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our products may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the negligence of one of our suppliers in supplying us with a defective component that injures a patient could be the basis for a claim against us. A product liability claim, regardless of its merit

or eventual outcome, could result in decreased demand for our products; injury to our reputation; diversion of management's attention; withdrawal of clinical trial participants; significant costs of related litigation; substantial monetary awards to patients; product recalls or market withdrawals; loss of revenue; and the inability to commercialize our products under development.

Risks Related to our Intellectual Property

If we are unable to obtain or maintain intellectual property rights relating to our technology and neuroblocking therapy, the commercial value of our technology and any future products will be adversely affected and our competitive position will be harmed.

Our commercial success depends in part on our ability to obtain protection in the United States and other countries for our Lap-Band System, Obalon Balloon System, and DBSN device by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. We own numerous U.S. and foreign patents and have numerous patent applications pending, most of which pertain to treating gastrointestinal disorders and the treatment of obesity. We have also received or applied for additional patents outside the United States. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. We expect to incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third-party's products or patents in litigation or administrative proceedings, including patent interferences, re-examinations or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies.

We cannot assure you that we will obtain any patent protection that we seek, that any protection we do obtain will be found valid and enforceable if challenged or that it will confer any significant commercial advantage. U.S. patents and patent applications may also be subject to interference proceedings and U.S. patents may be subject to re-examination proceedings in the USPTO, or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices, which proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of, the patent or patent application. In addition, such interference, re-examination and opposition proceedings may be costly. Moreover, the U.S. patent laws have recently changed with the adoption of the America Invents Act ("AIA"), possibly making it easier to challenge patents. Some of our technology was, and continues to be, developed in conjunction with third parties, and thus there is a risk that such third parties may claim rights in our intellectual property. Thus, any patents that we own or license from others may provide limited or no protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology.

We may lose important patents or patent rights if we do not timely pay required patent fees or annuities.

We have, from time to time, experienced delays in the payment of required patent fees or annuities. Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may result in

loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical products and procedures.

Many of our competitors have significant resources and incentives to apply for and obtain intellectual property rights that could limit or prevent our ability to commercialize our current or future products in the United States or abroad.

Many of our competitors who have significant resources and have made substantial investments in competing technologies may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the U.S. or in international markets. Our current or future U.S. or foreign patents may be challenged, circumvented by competitors or others or may be found to be invalid, unenforceable or insufficient. In most cases in the United States patent applications are published 18 months after filing the application, or corresponding applications are published in other countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our pending patent applications, or that we were the first to file patent applications for such inventions.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Intellectual property litigation is a common tactic in the medical device industry to gain competitive advantage. If we become subject to a lawsuit, we may be required to expend significant financial and other resources and our management's attention may be diverted from our business.

There has been a history of frequent and extensive litigation regarding patent and other intellectual property rights in the medical device industry, and companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Accordingly, we may become subject to patent infringement claims or litigation in a court of law, or interference proceedings declared by the USPTO to determine the priority of inventions or an opposition to a patent grant in a foreign jurisdiction. We may also become subject to claims or litigation seeking payment of royalties based on sales of our product in connection with licensing or similar joint development arrangements with third parties or in connection with claims of patent infringement.

The defense and prosecution of intellectual property suits, USPTO interference proceedings, reexamination proceedings, or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, or opposition proceedings and related legal and administrative proceedings, are both costly and time consuming and could result in substantial uncertainty to us. Litigation or regulatory proceedings may also be necessary to enforce patent or other intellectual property rights of ours or to determine the scope and validity of other parties' proprietary rights. Any litigation, opposition or interference proceedings, with or without merit, may result in substantial expense to us, cause significant strain on our financial resources, divert the attention of our technical and management personnel and harm our reputation. We may not have the financial resources to defend our patents from infringement or claims of invalidity. An adverse determination in any litigation could subject us to significant liabilities to

third parties, require us to seek licenses from or pay royalties to third parties or prevent us from manufacturing, selling or using our proposed products, any of which could have a material adverse effect on our business and prospects.

Our Lap-Band System, Obalon Balloon System or DBSN device may infringe or be claimed to infringe patents that we do not own or license, including patents that may issue in the future based on patent applications of which we are currently aware, as well as applications of which we are unaware. For example, we are aware of other companies that are investigating neurostimulation, including neuroblocking, and of patents and published patent applications held by companies in those fields. While we believe that none of such patents and patent applications are applicable to our products and technologies under development, third parties who own or control these patents and patent applications in the United States and abroad could bring claims against us that would cause us to incur substantial expenses and, if such claims are successfully asserted against us, they could cause us to pay substantial damages, could result in an injunction preventing us from selling, manufacturing or using our proposed products and would divert management's attention. Because patent applications in many countries such as the United States are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware, and which may later result in issued patents that our products infringe. If a patent infringement suit were brought against us, we could be forced to stop our ongoing or planned clinical trials, or delay or abandon commercialization of the product that is subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties, or both. A license may not be available at all or on commercially reasonable terms, and we may not be able to redesign our products to avoid infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

We may in the future become involved in lawsuits, to protect or enforce our intellectual property, which can be expensive and time consuming and could result in the diversion of significant resources.

Adverse proceedings such as litigation or challenges to the validity of our patents can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. In addition, in an infringement or other adverse proceeding, a court may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question. An adverse result in any litigation or proceeding could place one or more of our patents at risk of being invalidated, interpreted narrowly or found unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us, if we assert our rights against them.

Risks Relating to Ownership of our Common Stock

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The trading price of our common stock has been highly volatile. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals of our product or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development milestones and to do so in accordance with the timing estimates we have publicly announced;

- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- changes in government regulations and standards affecting the medical device industry and our product;
- ability of our products to achieve market success;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to develop sales and marketing capabilities;
- actual or anticipated variations in our results of operations or those of our competitors;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;
- decreases in market valuations of medical device companies;
- our pending Merger and Asset Sale; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

The stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, securities class action litigation often has been initiated against a company. If class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations, which could significantly harm our business.

Sales of a substantial number of shares of our common stock in the public market by us or by our existing stockholders, or the perception that they may occur, could cause our stock price to decline.

Sales of substantial amounts of our common stock by us, including in connection with this offering, or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital, upon the exercise of options or warrants, or in connection with acquisitions or corporate alliances, including the Merger. We also plan to issue additional shares to our employees, directors or consultants in connection with their services to us. All of the currently outstanding shares of our common stock are freely tradable under federal and state securities laws, except for shares held by our directors, officers and certain greater than five percent stockholders, which may be subject to holding period, volume and other limitations under Rule 144. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time and could reduce the market price of our common stock.

We have a significant number of outstanding warrants, which may cause significant dilution to our stockholders, have a material adverse impact on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings.

As of July 8, 2024, the date of the Merger Agreement and Asset Purchase Agreement, we had outstanding 508,735 shares of common stock. In addition, we had outstanding warrants to acquire 82,440

shares of common stock. The issuance of shares of common stock upon the exercise of warrants would dilute the percentage ownership interest of all stockholders, might dilute the book value per share of our common stock and would increase the number of our publicly traded shares, which could depress the market price of our common stock.

In addition to the dilutive effects described above, the perceived risk of dilution as a result of the significant number of outstanding warrants may cause our common stockholders to be more inclined to sell their shares, which would contribute to a downward movement in the price of our common stock. Moreover, the perceived risk of dilution and the resulting downward pressure on our common stock price could encourage investors to engage in short sales of our common stock, which could further contribute to price declines in our common stock. The fact that our stockholders and warrant holders can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional funds through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all.

If we fail to meet all applicable Nasdaq Capital Market requirements, Nasdaq could delist our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Nasdaq monitors our ongoing compliance with its minimum listing requirements and if we fail to meet those requirements and cannot cure such failure in the prescribed period of time, our common stock could be subject to delisting from the Nasdaq market. In the event that our common stock is delisted from the Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

For example, on October 10, 2023, we received a written notice from The Nasdaq Stock Market indicating that we were not in compliance with the $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. The notice provided that we had until April 7, 2024 to regain compliance. In order to regain compliance with the bid price requirement, on February 23, 2024, the stockholders of ReShape authorized for the Board, in its discretion but no later than February 23, 2025, to declare a reverse stock split at a ratio in the range of 1-for-10 to 1-for-60, such ratio to be determined by the Board. On April 9, 2024, the Company received a written notice from the Nasdaq Staff that the Company has not regained compliance with the minimum $1.00 bid price requirement. However, the Nasdaq Staff has determined that the Company is eligible for an additional 180 calendar period, or until October 7, 2024, to regain compliance. If at any time during this period the closing bid price of the Company's common stock is at least $1.00 per share for a minimum of 10 consecutive business days, the Nasdaq Staff will provide the Company with a written confirmation of compliance and the matter will be closed. If compliance cannot be demonstrated by October 6, 2024, the Nasdaq Staff will provide written notification that the Company's common stock will be delisted. At that time, the Company may appeal the Nasdaq Staff's determination to a Hearings Panel. On September 23, 2024, ReShape effected a reverse stock split of the ReShape Shares at a ratio of 1-for-58 and on October 7, 2024 the Nasdaq Staff notified ReShape that it has regained compliance with the bid price requirement and the matter is now closed. However, pursuant to Listing Rule 5810(c)(3)(A)(iv), if the Company's common stock fails to meet the continued listing requirement for minimum bid price between the date of this prospectus and October 7, 2025 or if the Company effects a second reverse stock split prior to September 23, 2026 with a cumulative ratio of 250 shares or more to one, then the Company will be issued a Staff Delisting Determination upon such non-compliance.

On November 25, 2024, we received a written notice from Nasdaq indicating that we are not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires companies listed on the Nasdaq Capital Market to maintain a minimum of $2.5 million in stockholders' equity for continued listing. As of September 30, 2024, our stockholders' equity was $1,487,000. Under the Nasdaq Listing Rules we had

45 calendar days to submit a plan to regain compliance, which we timely submitted on January 9, 2025 and Nasdaq has granted us an extension through May 27, 2025 to regain compliance.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital for general corporate purposes, in the future we may offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings.

Our organizational documents and Delaware law make a takeover of our company more difficult, which may prevent certain changes in control and limit the market price of our common stock.

The Restated Certificate of Incorporation of ReShape, as amended (our "charter"), and the Amended and Restated Bylaws of ReShape (our "bylaws") and Section 203 of the Delaware General Corporation Law contain provisions that may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. These provisions include:

- the ability of the Board to create and issue preferred stock without stockholder approval, which could be used to implement anti-takeover devices;
- the authority for the Board to issue without stockholder approval up to the number of shares of common stock authorized in the charter, that, if issued, would dilute the ownership of our stockholders;
- the advance notice requirement for director nominations or for proposals that can be acted upon at stockholder meetings;
- a classified and staggered board of directors, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors;
- the prohibition on actions by written consent of our stockholders;
- the limitation on who may call a special meeting of stockholders;
- the prohibition on stockholders accumulating their votes for the election of directors; and
- the ability of stockholders to amend the bylaws only upon receiving a majority of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

These provisions also could discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Some provisions in the charter and bylaws may deter third parties from acquiring us, which may limit the market price of our common stock.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our common stock.

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the Board may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Risks Related to the Asset Sale

While the Asset Sale is pending, it creates unknown impacts on our future which could materially and adversely affect its business, financial condition and results of operations.

While the Asset Sale is pending, it creates unknown impacts on our future. Therefore, our current or potential business partners may decide to delay, defer or cancel entering into new business arrangements with ReShape pending consummation of the Asset Sale. The occurrence of these events individually or in combination could materially and adversely affect our business, financial condition and results of operations.

The failure to consummate the Asset Sale may materially and adversely affect our business, financial condition and results of operations.

The Asset Sale is subject to various closing conditions including, among others, the approval of the Asset Sale by ReShape's stockholders. ReShape cannot control these conditions and cannot assure you that they will be satisfied. If the Asset Sale is not consummated, ReShape may be subject to a number of risks, including the following:

- we may not be able to identify an alternate transaction, or if an alternate transaction is identified, such alternate transaction may not result in equivalent terms as compared to what is proposed in the Asset Sale;
- the trading price of our common stock may decline to the extent that the current market price reflects a market assumption that the Asset Sale will be consummated;
- doubt as to our ability to effectively implement its current and future business strategies;
- our costs related to the Asset Sale, such as legal, accounting and financial advisory fees, must be paid even if the Asset Sale is not completed; and
- our relationships with its customers, suppliers and employees may be damaged and its business may be harmed.

The occurrence of any of these events individually or in combination could materially and adversely affect our business, financial condition and results of operations, which could cause the market value of our common stock to decline.

The Merger may be consummated despite the Asset Sale not closing under certain circumstances.

While the closing of the Merger is conditioned on the closing of the Asset Sale, if we fail to consummate the Asset Sale, the Merger may still proceed, provided that the closing condition related to the closing of the Asset Sale contained in the Merger Agreement is waived by Vyome. The occurrence of these events would result in the Combined Company continuing to own the assets currently contemplated to be sold to Ninjour as part of the Asset Sale following the closing of the Merger, which could cause the Combined Company to incur unanticipated costs and expenses in connection with continued ownership of such assets, or pursuit of an alternative disposition of such assets. Further, in such an event, the Combined Company may also be subject to any disputes/ litigation filed in respect of the assets to be sold as part of the Asset Sale. Any such liabilities or problems could have an adverse effect on the Combined Company's business, financial condition, results of operations or cash flows.

Risks Relating to this Offering

Management will have broad discretion as to the use of the net proceeds from this offering, and we may not use these proceeds effectively.

We intend to use the net proceeds from this offering for working capital and general corporate purposes, including expenses related to our previously announced proposed merger with Vyome Therapeutics, Inc. and sale of substantially all of our assets to Ninjour Health International Limited, provided that under the terms of the Securities Purchase Agreement for the Convertible Note transaction with Ascent, we must use up to 50% of the net proceeds from any issuance of capital stock to prepay the amount we owe to Ascent under the Convertible Note. As a result, our management will have broad discretion in the application of the remaining 50% of the net proceeds from this offering and could spend these proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used effectively. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock.

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. If there are more shares of our common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may decline to a market price at which buyers are willing to purchase the offered shares of our common stock and sellers remain willing to sell the shares. All of the securities issued in the offering will be freely tradable without restriction or further registration under the Securities Act.

This is a best efforts offering, and no minimum number or dollar amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

The Placement Agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The Placement Agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth in this prospectus. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to fund research and development of our lead product candidates, including clinical trial activities. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

You will experience immediate dilution in the net tangible book value per share of the Common Stock you purchase, and may experience additional dilution in the future.

Because the effective price per Unit being offered hereby may be higher than the net tangible book value per share of our Common Stock, you may experience dilution to the extent of the difference between the effective offering price per Unit you pay in this offering and the net tangible book value per share of our Common Stock immediately after this offering. Assuming the sale of 1,779,360 Units at a public offering price of $2.81 per Unit and our net tangible book value as of September 30, 2024, assuming no sale of any Pre-funded Warrants in this offering and no exercises of Warrants, and after deducting the placement agent fees and estimated offering expenses payable by us, you will incur immediate dilution in as adjusted net tangible book value of approximately $0.42 per share. As a result of the dilution to investors purchasing

securities in this offering, investors may receive less than the purchase price paid in this offering, if anything, in the event of the liquidation of our company. See the section entitled "*Dilution*" below for a more detailed discussion of the dilution you will incur if you participate in this offering.

This offering may cause the trading price of our Common Stock to decrease.

The number of shares of Common Stock, Pre-funded Warrants and Warrants we propose to issue and ultimately will issue if this offering is completed, may result in an immediate decrease in the market price of our Common Stock. This decrease may continue after the completion of this offering. We cannot predict the effect, if any, that the availability of shares for future sale represented by the Pre-funded Warrants and Warrants issued in connection with the offering will have on the market price of our Common Stock from time to time, but future exercises may also result in a decrease in the market price of our Common Stock.

There is no public market for the Warrants or Pre-funded Warrants being offered by us in this offering.

There is no established public trading market for the Warrants or Pre-funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants or Pre-funded Warrants on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the Warrants and Pre-funded Warrants will be limited.

Except as otherwise set forth in the Warrants or Pre-funded Warrants, holders of the Warrants or Pre-funded Warrants offered hereby will have no rights as stockholders with respect to the shares of Common Stock underlying the Warrants or Pre-funded Warrants until such holders exercise their Warrants or Pre-funded Warrants and acquire our Common Stock.

Except as otherwise set forth in the Warrants or Pre-funded Warrants, until holders of the Warrants or Pre-funded Warrants acquire shares of our Common Stock upon exercise thereof, such holders of the Warrants or Pre-funded Warrants will have no rights with respect to the shares of our Common Stock underlying such warrants, such as voting rights. Upon exercise of the Pre-funded Warrants, as the case may be, the holder will be entitled to exercise the rights of a Common Stockholder only as to matters for which the record date occurs after the exercise date.

If the Warrants are exercised by way of an alternative cashless exercise, especially after the reset date stockholders may suffer substantial dilution.

If the Warrants are exercised by way of an alternative cashless exercise, assuming receipt of Warrant Stockholder Approval, such exercising holder will receive 1.2 shares of Common Stock for each Warrant they exercise, without any cash payment to us. Further, on the Reset Date, if the lowest VWAP for our Common Stock during the period beginning four trading days prior to the effective date of Warrant Stockholder Approval and ending four trading days after the date of Warrant Stockholder Approval is lower than the then exercise price of the Warrants, then on the Reset Date, the exercise price of the Warrants will be reset (subject to a floor of $1.25 per share) to equal such lowest VWAP and the number of shares of Common Stock underlying the Warrants will be increased so that the reset exercise price multiplied by increased number of shares equals the aggregate proceeds that would have resulted from the full exercise of the Warrants immediately prior to the Rest Date. If an alternative cashless exercise occurs, such exercise will result in substantial dilution to stockholders and if such alternative cashless exercise occurs after the Reset Date, the dilution will be even more substantial.

We will likely not receive any additional funds upon the exercise of the Warrants.

If we receive the Warrant Stockholder Approval, the Warrants may be exercised by way of an alternative cashless exercise, in which case the holder would not pay a cash purchase price upon exercise, but instead would receive upon such exercise the number of shares equal to the number of Warrants being exercised multiplied by 1.2. Accordingly, we will likely not receive any additional funds upon the exercise of the Warrants.

The Warrants are not exercisable unless and until Warrant Stockholder Approval is obtained from our stockholders. Further, even if we obtain Warrant Stockholder Approval, the Warrants may only be exercisable for a limited period of time.

The Warrants are only exercisable upon receipt of Warrant Stockholder Approval. While we intend to promptly seek Warrant Stockholder Approval, there is no guarantee that the Warrant Stockholder Approval will ever be obtained. If we are unable to obtain the Warrant Stockholder Approval, the Warrants may have no value. Further, even if we obtain Warrant Stockholder Approval, the Warrants may only be exercisable for a limited period of time. Specifically, depending on the timing of closing of the Merger, holders of the Warrants may only have a limited opportunity to exercise their Warrants. Accordingly, the Warrants may expire with limited or not value to the holders.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims for breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including timely delivery of shares and indemnification for breach of contract.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this prospectus, or filings with the SEC and our public releases, that are not purely historical are forward-looking statements within the meaning of applicable securities laws. Our forward-looking statements include, but are not limited to, statements regarding our "expectations," "hopes," "beliefs," "intentions" or "strategies" regarding the future. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should" and "would," as well as similar expressions, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward looking. Such statements include, but are not limited to, statements contained in this prospectus relating to our business strategy, our future operating results and liquidity and capital resources outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, our ability to raise capital to fund continuing operations; our ability to protect our intellectual property rights; the impact of any infringement actions or other litigation brought against us; competition from other providers and products; our ability to develop and commercialize products and services; changes in government regulation; our ability to complete capital raising transactions; and other factors (including the risks contained in the section of this prospectus entitled "*Risk Factors*") relating to our industry, our operations and results of operations. Actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

This prospectus may contain assumptions, expectations, projections, intentions and beliefs about future events. These statements are intended as forward-looking statements. We may also from time to time make forward-looking statements in other documents and reports that are filed with or submitted to the SEC, in other information sent to our security holders, and in other written materials. We also caution that assumptions, expectations, projections, intentions and beliefs about future events may and often do vary from actual results and the differences can be material.

CAPITALIZATION

The following table shows our cash and cash equivalents and capitalization as of September 30, 2024 as follows:

- on an actual basis;
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 1,779,360 Units in this offering (assuming the maximum amount of is sold and no sale of any Units containing a Pre-funded Warrant) at a public offering price of $2.81 per Unit, resulting in net proceeds to us of $4,450,000 after deducting estimated placement agent fees and estimated offering expenses payable.

The pro forma information below is illustrative only and our capitalization following the completion of this offering is subject to adjustment based on the public offering price of our Units and other terms of this offering determined at pricing. You should read the following table in conjunction with "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included in this prospectus.

	As of September 30, 2024		
	Actual	Pro Forma Adjustments	Pro Forma Adjusted
Cash and cash equivalents	$ 743	$4,450	$ 5,193
Stockholders' equity:			
Preferred stock	—	—	—
Common Stock	—	2	2
APIC	642,518	4,448	646,966
Accumulated deficit	(640,943)	—	(640,943)
Accumulated other	(88)	—	(88)
Total Equity	$ 1,487	$4,450	$ 5,937

DILUTION

If you invest in our Units in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per Unit and the as adjusted net tangible book value per share of our Common Stock immediately after this offering.

Our historical net tangible book value (deficit) as of September 30, 2024, was $1,487,000. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities. Our historical net tangible book value per share as of September 30, 2024, was $2.11. Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the number of shares of our Common Stock outstanding as of September 30, 2024.

After giving effect to our issuance and sale of 1,779,360 Units in this offering at an assumed public offering price of $2.81 per Unit (the closing sale price of our Common Stock on the Nasdaq Stock Market, LLC on January 31, 2025), assuming no Units included any Pre-funded Warrants in this offering and after deducting placement agent fees and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2024 would have been approximately $5,937,000, or approximately $2.39 per share. This represents an immediate increase in actual net tangible book value per share of $0.28 to our existing stockholders and an immediate dilution in actual net tangible book value per share of approximately $0.42 to new investors purchasing Units in this offering. Dilution per share to new investors purchasing Common Stock in this offering is determined by subtracting as adjusted net tangible book value per share after this offering from the public offering price per Unit paid by new investors.

The following table illustrates this dilution on a per share basis:

Assumed Public offering price per Unit	$2.81
Actual net tangible book value per share as of September 30, 2024	$2.11
Increase in actual net tangible book value (deficit) per share as of September 30, 2024	$0.28
Pro forma as adjusted net tangible book value per share after this offering	$2.39
Dilution per share to new investors purchasing shares in this offering	$0.42

The table and discussion above are based on 704,697 shares of Common stock outstanding as of September 30, 2024 and excludes the following that were outstanding as of such date:

- 144 shares of common stock issuable upon the exercise of outstanding options granted under our equity incentive plans at a weighted average exercise price of $34,101.10 per share;
- 81,432 shares of common stock issuable upon the exercise of outstanding warrants;
- 8 shares of common stock issuable upon vesting of outstanding restricted stock units; and
- 81,432 shares of common stock issuable upon the exercise of outstanding warrants.

If we only sell 75% or 50% of the maximum offering amount, our as adjusted net tangible book value after this offering would be $4,775,000, or $3,612,000, respectively, and the dilution per share to investors purchasing securities in this offering would be $0.47 or $0.54, respectively, assuming no Units including Pre-funded Warrants are sold and after deducting placement agent fees and estimated offering expenses payable by us.

The information discussed above is illustrative only and will be adjusted based on the actual public offering price, the actual number of units that we offer in this offering, and other terms of this offering determined at the time of pricing. The foregoing discussion and table assumes no sale of Units including Pre-funded Warrants, which if sold, would reduce the number of shares that we are offering on a one-for-one basis. It also assumes no exercises of the Warrants issued as part of the Units. In addition, we may choose to raise additional capital due to market conditions or strategic considerations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

USE OF PROCEEDS

Assuming all of the securities offered in this offering are sold, we estimate that our net proceeds from this offering will be approximately $4,450,000, after deducting placement agent fees and estimated offering expenses payable by us, based on an assumed offering price of $2.81 per share, the last reported sale price of our common stock on the Nasdaq Capital Market on February 10, 2025. We estimate that our net proceeds from the sale of 75% of the securities offered in this offering will be approximately $3,287,500, after deducting placement agent fees and estimated offering expenses payable by us, based on an assumed offering price of $2.81 per share, equal to the closing price of our common stock on Nasdaq on February 10, 2025. We estimate that our net proceeds from the sale of 50% of the securities offered in this offering will be approximately $2,125,000, after deducting placement agent fees and estimated offering expenses payable by us, based on an assumed offering price of $2.81 per share, equal to the closing price of our common stock on Nasdaq on February 10, 2025. However, because this is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus.

We expect to use the net proceeds from this offering for general corporate purposes, including expenses related to our previously announced proposed merger with Vyome Therapeutics, Inc. and sale of substantially all of our assets to Ninjour Health International Limited, provided that under the terms of the Securities Purchase Agreement for the Convertible Note transaction with Ascent, we must use up to 50% of the net proceeds from any issuance of capital stock, including under an equity line of credit, to prepay the amount we owe to Ascent under the Convertible Note. We will have discretion over the remaining portion of the net proceeds and may find it necessary or advisable to use those proceeds for other purposes not described above.

The Convertible Note bears interest at a rate of 10% per annum and is due and payable on the earlier of (i) April 14, 2025 and (ii) the date of consummation or termination of our previously announced merger with Vyome Therapeutics, Inc. The initial conversion price of the Convertible Note is $5.22 per share of common stock. The Note provides for certain events of default that are typical for a transaction of this type, including, among other things, any breach of the representations or warranties made by the company or our subsidiaries. In connection with any event of default that results in the acceleration of payment of the Convertible Note and while it is continuing, the interest rate on the Convertible Note shall accrue at an interest rate equal to the lesser of 24% per annum or the maximum rate permitted under applicable law. The proceeds from the Convertible Note transaction are being used for general corporate purposes, including related to our previously announced proposed merger with Vyome Therapeutics, Inc. and sale of substantially all of our assets to Ninjour Health International Limited.

We will have broad discretion over the use of any proceeds from the sales of our securities in this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the factors described under "*Risk Factors*" in this prospectus and in any accompanying prospectus supplements, as well as the amount of cash used in our operations.

MARKET AND DIVIDEND INFORMATION FOR OUR COMMON STOCK

Market Information

Our common stock is listed on the Nasdaq Capital Market under the ticker symbol “RSLS.”

Holders of Record

As of January 15, 2025, we had 40 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose common stock may be held in trust or by other entities.

Dividends

We have not paid any cash dividends and do not expect to do so in the foreseeable future.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of ReShape's financial condition and results of operations together with its consolidated financial statements and related notes thereto included elsewhere in this proxy/information statement-prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this proxy/information statement-prospectus, including information with respect to ReShape's plans and strategy for its business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the "cautionary statement regarding forward- looking statements" and "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are the premier global weight-loss solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and associated metabolic disease. Our primary operations are in the following geographical areas: United States, Australia and certain European and Middle Eastern countries. Our current portfolio includes the Lap-Band Adjustable Gastric Banding System, the Obalon Balloon System, and the Diabetes Bloc-Stim Neuromodulation device, a technology under development as a new treatment for type 2 diabetes mellitus. There has been no revenue recorded for the Obalon Balloon System, or the Diabetes Bloc-Stim Neuromodulation as these products are still in the development stage.

Year Ended December 31, 2023

Recent Developments

In February 2024, the Company announced the first surgeries utilizing the Lap-Band 2.0 FLEX mark, not only a seminal moment in the Company's launch of this enhanced product, but also a leap forward in improving the Lap-Band.

On July 8, 2024, we entered into the Merger Agreemenet and Asset Purchase Agreement.

In a private transaction, on October 16, 2024, the Company entered into a securities purchase agreement (the "SPA") with Ascent. Pursuant to the SPA, the Company agreed to issue to Ascent a senior secured convertible note in the aggregate original principal amount of $833,333.34 (the "Note"), and also issued to Ascent 7,983 shares of ReShape Common Stock as "commitment shares" to Ascent. The Company is the issuer of the Note, and the Company's subsidiaries are guaranteeing the obligations under the Note pursuant to a Guaranty, dated October 16, 2024. The Note is fully secured by collateral of the Company and its subsidiaries. The security interest in favor of Ascent, as collateral agent, covers substantially all assets of the Company including, without limitation, the intellectual property, trademark, and patent rights of the Company. The parties entered into a Security Agreement and certain intellectual property security agreements granting such security interest in favor of Ascent.

On December 19, 2024, the Company entered into an equity purchase agreement (the "EPA") with Ascent, pursuant to which Ascent agreed to purchase from the Company, at the Company's direction and from time to time, in its sole discretion, from and after the effectiveness of the definitive documentation (the "Effective Date"), and until the earlier of (i) the 36-month anniversary of the Effective Date or (ii) the termination of the EPA in accordance with the terms thereof, shares of the Company's common stock having a total maximum aggregate purchase price of $5,000,000, upon the terms and subject to the conditions and limitations set forth therein.

In connection with the EPA, the Company filed a Registration Statement on Form S-1 on December 20, 2024 to register the issuance of 17,300 shares of the Company's common stock to Ascent and 21,015 shares issuable upon exercise of a pre-funded warrant. Ascent agreed to hold such shares through the date of the ReShape Special Meeting to approve the Merger and Asset Sale and agreed to vote such shares in favor of all management proposals at such meeting.

Financial Overview

Results of Operations

The following table sets forth certain data from our operating results from the years ended December 31, 2023 and 2022, expressed as percentages of revenue (in thousands):

	Year Ended December 31,			
	2023		2022	
Revenue	$ 8,678	100.0%	$ 11,240	100.0%
Cost of revenue	3,130	36.1%	4,438	39.5%
Gross profit	5,548	63.9%	6,802	60.5%
Operating expenses:				
Sales and marketing	7,548	87.0%	14,093	125.4%
General and administrative	10,324	119.0%	17,250	153.5%
Research and development	2,315	26.7%	2,537	22.6%
Impairment of long-lived assets	777	9.0%	18,744	166.8%
(Gain) loss on disposal of assets, net	(33)	(0.4)%	529	4.7%
Total operating expenses	20,931	241.3%	53,153	473.0%
Operating loss	(15,383)	(177.4)%	(46,351)	(412.5)%
Other expense (income), net:				
Interest (income) expense, net	(26)	(0.3)%	113	1.0%
Gain on changes in fair value of liability warrants	(3,878)	(44.7)%	—	—%
(Gain) loss on foreign currency exchange, net	(22)	(0.3)%	141	1.3%
Other	(122)	(1.4)%	(11)	(0.1)%
Loss before income tax provision	(11,335)	(130.7)%	(46,594)	(414.7)%
Income tax expense (benefit)	52	0.6%	(380)	(3.4)%
Net loss	$(11,387)	(131.2)%	$(46,214)	(411.2)%

Non-GAAP Disclosures

In addition to the financial information prepared in conformity with GAAP, we provide certain historical non-GAAP financial information. Management believes that these non-GAAP financial measures assist investors in making comparisons of period-to-period operating results and that, in some respects, these non-GAAP financial measures are more indicative of the Company's ongoing core operating performance than their GAAP equivalents.

Management believes that the presentation of this non-GAAP financial information provides investors with greater transparency and facilitates comparison of operating results across a broad spectrum of companies with varying capital structures, compensation strategies, derivative instruments, and amortization methods, which provides a more complete understanding of our financial performance, competitive position, and prospects for the future. However, the non-GAAP financial measures presented in this proxy/information statement-prospectus have certain limitations in that they do not reflect all of the costs associated with the operations of our business as determined in accordance with GAAP. Therefore, investors should consider non-GAAP financial measures in addition to, and not as a substitute for, or as superior to, measures of financial performance prepared in accordance with GAAP. Further, the non-GAAP financial measures presented by the Company may be different from similarly named non-GAAP financial measures used by other companies.

Adjusted EBITDA

Management uses Adjusted EBITDA in its evaluation of the Company's core results of operations and trends between fiscal periods and believes that these measures are important components of its internal

performance measurement process. Adjusted EBITDA is defined as net loss before interest, taxes, depreciation and amortization, stock-based compensation, and other one-time costs. Therefore, investors should consider non-GAAP financial measures in addition to, and not as a substitute for, or as superior to, measures of financial performance prepared in accordance with GAAP. Further, the non-GAAP financial measures presented by the Company may be different from similarly named non-GAAP financial measures used by other companies.

The following table contains a reconciliation of GAAP net loss to non-GAAP net loss attributable to common stockholders for the years ended December 31, 2023 and 2022 (in thousands).

	Year Ended December 31,	
	2023	2022
GAAP net loss	$(11,387)	$(46,214)
Adjustments:		
Interest (income) expense, net	(26)	113
Income tax expense (benefit)	52	(380)
Depreciation and amortization	154	2,153
Stock-based compensation expense	767	2,087
Impairment of long-lived assets	777	18,744
(Gain) loss on disposal of assets, net	(33)	529
Gain on changes in fair value of liability warrants	(3,878)	—
Adjusted EBITDA	$(13,574)	$(22,968)

Comparison of Results of Operations

Revenue. The following table summarizes our net revenue by geographic location based on the location of customers for the years ended December 31, 2023 and 2022, as well as the percentage by location of total revenue and the amount of change and percentage of change (dollars in thousands):

	Year Ended December 31,				Amount Change	Percentage Change
	2023		2022			
United States	$7,134	82.2%	$ 9,230	82.2%	$(2,096)	(22.7)%
Australia	526	6.1%	688	6.1%	(162)	(23.5)%
Europe	956	11.0%	1,252	11.1%	(296)	(23.6)%
Rest of world	62	0.7%	70	0.6%	(8)	(11.4)%
Total revenue	$8,678	100.0%	$11,240	100.0%	$(2,562)	(22.8)%

Revenue totaled $8.7 million for the year ended December 31, 2023, which represents a contraction of 22.8%, or $2.6 million compared to the same period in 2022. The primary reason for the decrease is due to the introduction of GLP-1 pharmaceuticals within the US. This is also evidenced by a decrease of Lap-Band unit sales of approximately 26.8%.

Cost of Revenue and Gross Profit: The following table summarizes our cost of goods sold and gross profit for the years ended December 31, 2023 and 2022, as well as percentage of total revenue and the amount of change and percentage of change (dollars in thousands):

	Year Ended December 31,				Amount Change	Percentage Change
	2023		2022			
Revenue	$8,678	100.0%	$11,240	100.0%	$(2,562)	(22.8)%
Cost of revenue	3,130	36.1%	4,438	39.5%	(1,308)	(29.5)%
Gross profit	$5,548	63.9%	$ 6,802	60.5%	$(1,254)	(18.4)%

Gross profit. Gross profit for the year ended December 31, 2023, was $5.5 million, compared to $6.8 million for the year ended December 31, 2022, a decrease of $1.3 million or 18.4%. Gross profit as

a percentage of revenue for the year ended December 31, 2023, was 63.9% compared to 60.5% for the same period in 2022. The increase in gross profit margin is primarily due to the Company allocating resources that were previously primarily focused on inventory to other projects and allocated a larger percentage of these costs to operating expenses in 2023.

Operating Expenses: The following table summarizes our operating expenses for the years ended December 31, 2023 and 2022, as well as the percentage of total revenue, and the amount of changes and percentage of change (dollars in thousands):

	Year Ended December 31,				Amount Change	Percentage Change
	2023		2022			
Sales and marketing	$ 7,548	87.0%	$14,093	125.4%	$ (6,545)	(46.4)%
General and administrative	10,324	119.0%	17,250	153.5%	(6,926)	(40.2)%
Research and development	2,315	26.7%	2,537	22.6%	(222)	(8.8)%
Impairment of long-lived assets	777	9.0%	18,744	166.8%	(17,967)	(95.9)%
(Gain) loss on disposal of assets, net	(33)	(0.4)%	529.0	4.7%	(562)	(106.2)%
Total operating expenses	$20,931	241.3%	$53,153	472.9%	$(32,222)	(60.6)%

Sales and Marketing Expense. Sales and marketing expenses for the year ended December 31, 2023, decreased by $6.6 million, or 46.4%, to approximately $7.5 million, compared to $14.1 million for the same period in 2022. The decrease is primarily due to a decrease of $5.2 million in advertising and marketing expenses, including consulting and professional marketing services, as the Company has reevaluated its marketing approach and has moved to a targeted digital marketing campaign, resulting in a significant reduction of costs. We also had reductions in payroll expenditures, including commissions, travel and stock-based compensation of $1.2 million, due to changes in sales personnel and lower sales.

General and Administrative Expense. General and administrative expenses for the year ended December 31, 2023, decreased by approximately $7.0 million, or 40.2%, to approximately $10.3 million, compared to $17.3 million for the same period in 2022. The decrease is primarily due to a reduction in legal related expenses due to the Company recording $2.6 million in litigation losses during the year ended December 31, 2022. In addition, the Company had a reduction in payroll related expenses including stock-based compensation expense of $2.8 million, due to changes within personnel. We had a decrease in intangible asset amortization of $1.8 million, as we impaired our finite intangible assets during the fourth quarter of 2022. We also had a decrease in rent and insurance of $0.7 million due to the lease of our former Carlsbad, CA location expiring. We also had a decrease of $0.3 million related to non-income taxes. This was offset by an increase in audit and professional services of approximately $1.2 million, primarily due to the offerings we completed during 2023.

Research and Development Expense. Research and development expenses for the year ended December 31, 2023, decreased by $0.2 million, or 8.8%, to $2.3 million, compared to $2.5 million for the same period in 2022. The decrease is primarily due to a decrease of $0.1 million in payroll expenses, as the Company's revenue declined, the Company allocated personnel's time to other research and development projects to utilize the employees and a reduction of depreciation expense of $0.1 million as the Company impaired its fixed assets during 2023.

Impairment of Long-Lived Assets. Impairment of long-lived assets decreased by approximately $18.0 million for the year ended December 31, 2023, compared to the same period in the prior year. During the year ended December 31, 2023, the Company impaired approximately $0.8 million, consisting of fixed assets and intangible assets. During the year ended December 31, 2022, the Company recorded an impairment charge of $7.4 million of in-process IPR&D and trademarks related to the ReShape Vest due to the Company no longer continuing with clinical trials. In addition, due to a reduction in our market capitalization at year end the Company impaired the developed technology and trademarks for both the Lap-Band and Obalon Balloon of $8.9 million and $2.4 million, respectively, due to reduced projected near-term future net cash flows related to the Lap-Band and no near-term revenue for the Obalon Balloon.

(Gain) loss on disposal of assets, net. During 2023, the Company had a gain of approximately $33 thousand related to the sale of fully depreciated assets. During the year ended December 31, 2022, the Company disposed of $0.5 million, primarily of assets that were acquired from the merger with Obalon.

Liquidity and Capital Resources

We have financed our operations to date principally through the sale of equity securities and debt financings. During the years ended December 31, 2023 and 2022, we received proceeds of $17.6 million and $3.1 million, respectively, from securities sales and exercises of warrants by an institutional investor. As of December 31, 2023, we had $4.5 million of cash and cash equivalents, and $100 thousand of restricted cash.

The following table summarizes our change in cash and cash equivalents (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$(16,960)	$(21,902)
Net cash used in investing activates	(10)	(92)
Net cash provided by financing activities	17,574	3,130
Effect of exchange rate changes	—	4
Net change in cash and cash equivalents and restricted cash	$ 604	$(18,860)

Net Cash Used in Operating Activities

Net cash used in operating activities was $17.0 million and $21.9 million for the years ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023, net cash used in operating activities was primarily the result of our net loss of $11.4 million, partially offset by non-cash adjustments of loss on impairment of long-lived asset of $0.8 million, stock-based compensation expense of $0.8 million, provision for bad debt expense of $0.4 million, provision for excess and obsolete inventory of $0.3 million, depreciation expense of $0.1 million, offset by non-cash reductions of expense non-cash gains recognized related to changes in fair value of liability warrants of 3.9 million. This was offset by a positive impact to accounts receivable of $0.1 million and a negative impact to cash from inventory of $0.5 million, prepaid expenses of $0.2 million and accounts payable and accrued liabilities of $3.5 million and a decrease in warranty liabilities of $0.2 million.

Net cash used in operating activities was $21.9 million for the year ended December 31, 2022. For the year ended December 31, 2022, net cash used in operating activities was primarily the result of our net loss of $46.2 million, partially offset by non-cash adjustments of loss on impairment of intangible assets of $18.7 million, stock-based compensation expense of $2.1 million, amortization of intangible assets of $1.8 million, loss on disposal of assets of $0.5 million, provision for excess and obsolete inventory of $0.6 million, depreciation expense of $0.3 million, offset by non-cash reductions of expense for deferred taxes of $0.4 million. We show a negative cash impact to inventory of $1.2 million and warranty liability of $0.4 million. This was offset by a positive impact to accounts receivable of $0.7 million, prepaid expenses of $1.1 million and accounts payable and accrued liabilities of $0.5 million.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2023, was insignificant as the Company was focused on preserving cash.

Net cash used in investing activities for the year ended December 31, 2022, was $0.1 million, primarily related to tooling equipment.

Net Cash Provided by Financing

Net cash provided by financing activities was $17.6 million for the year ended December 31, 2023, as the Company completed multiple public offerings with proceeds of approximately $13.5 million and $4.1 million of warrants exercised during 2023.

Net cash provided by financing activities was $3.1 million for the year ended December 31, 2022, primarily due to proceeds of $2.5 million received from the exercises of warrants from an institutional investor and $0.6 million of securities sold to an institutional investor.

Operating Capital and Capital Expenditure Requirements

The Company's anticipated operations include plans to (i) grow sales and operations of the Company with the Lap-Band product line both domestically and internationally as well as to obtain cost savings synergies, (ii) introduce to the market Lap-Band 2.0 FLEX, (iii) continue development of the Diabetes Bloc-Stim Neuromodulation ("DBSN") device, (vi) identifying strategic merger and acquisition alternatives, (v) seek opportunities to find strategic partners to leverage our intellectual property portfolio and custom development services to provide third-party sales and licensing opportunities, and (vi) explore and capitalize on synergistic opportunities to expand our portfolio and offer future minimally invasive treatments and therapies in the obesity continuum of care. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing, and product development activities. If managements' plans don't develop, and the Company doesn't get additional cash raises, at the current burn rate, management expects to run out of cash during the fourth quarter of 2024.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our DBSN, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of the DBNS or other additional products and successfully deliver a commercial product to the market. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our DBNS, and any products that we may develop;
- the rate of market acceptance of our DBNS, and any other product candidates;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our Lap-Band, Obalon Balloon System, DBNS or our future products;
- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported

expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this proxy/information statement-prospectus, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Intangible Assets and Long-Lived Assets

We acquire intangible assets in connection with business combinations and asset purchases. The acquired intangible assets are recorded at fair value, which is determined based on a discounted cash flow analysis. The determination of fair value requires significant estimates, including, but not limited to, the amount and timing of projected future cash flows, the discount rate used to discount those cash flows, the assessment of the asset's life cycle, including the timing and expected costs to complete in-process projects, and the consideration of legal, technical, regulatory, economic, and competitive risks.

Developed technology acquired in business combinations is reviewed for impairment annually, or whenever an event occurs, or circumstances change that would indicate the carrying amount may be impaired. Additionally, management reviews the carrying amounts of other intangible and long-lived assets whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. The impairment reviews require significant estimates about fair value, including estimation of future cash flows, selection of an appropriate discount rate, and estimates of long-term growth rates.

Stock-based Compensation

We measure and recognize compensation expenses for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options and restricted stock units. The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. The Black-Scholes models require various highly judgmental assumptions, including stock price volatility, risk-free interest rate, and expected option term. Stock-based compensation expense is recorded net of estimated forfeitures.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the consolidated statements of operations.

Accounts Receivable Reserve

The Company provides reserves against accounts receivable for estimated losses that may result from a customer's inability to pay based on customer-specific analysis and general matters such as current assessments of past due balances, economic conditions and forecasts, and historical credit loss activity. Amounts determined to be uncollectible are charged or written-off against the reserve. Additionally, under the current expected credit loss model, we utilize historical loss rates based on number of days past due, adjusted to reflect current economic conditions and forecasts of future economic conditions.

Inventory Reserve

The Company establishes inventory reserves for obsolescence based upon specific identification of expired or unusable units with a corresponding provision included in cost of revenue.

Fair Value of Warrants

We analyze warrants to determine if the warrant instrument should be treated as a liability or equity. Based on the outcome of this analysis, we measure the fair value of the instrument using a Black-Scholes valuation model, bifurcated Black-Scholes valuation model or a Monte Carlo valuation model. Each of these models require various highly judgmental assumptions, including stock price volatility, risk-free interest rate, and expected term.

Recent Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements, for a discussion of new accounting standards that have been adopted and those not yet adopted.

Nine Months Ended September 30, 2024

Results of Operations

The following table sets forth certain data from our unaudited consolidated statements of operations expressed as percentages of revenue (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024		2023		2024		2023	
Revenue	$ 2,292	100.0%	$ 2,155	100.0%	$ 6,201	100.0%	$ 6,696	100.0%
Cost of revenue	853	37.2%	867	40.2%	2,463	39.7%	2,990	44.7%
Gross profit	1,439	62.8%	1,288	59.8%	3,738	60.3%	3,706	55.3%
Operating expenses:								
Sales and marketing	719	31.4%	1,791	83.1%	2,408	38.8%	6,150	91.8%
General and administrative	2,082	90.8%	2,058	95.5%	6,074	98.0%	8,724	130.3%
Research and development	399	17.4%	542	25.2%	1,282	20.7%	1,576	23.5%
Impairment of long-lived assets			777	36.1%			777	11.6%
Gain on disposal of assets, net	—	—%	—	—%	—	—%	(33)	(0.5)%
Total operating expenses	3,200	139.6%	5,168	239.9%	9,764	157.5%	17,194	256.7%
Operating loss	(1,761)	(76.8)%	(3,880)	(180.1)%	(6,026)	(97.2)%	(13,488)	(201.4)%
Other expense (income), net:								
Interest income, net	—	—%	(5)	(0.2)%	(13)	(0.2)%	(9)	(0.1)%
Gain on changes in fair value of liability warrants	(27)	(1.2)%	(412)	(19)%	(46)	(0.7)%	(3,850)	(57.5)%
Gain on extinguishment of debt	—	—%	—	—%	(429)	(6.9)%	—	—%
Loss (gain) on foreign currency exchange, net	(50)	(2.2)%	68	3.2%	(10)	(0.2)%	47	0.7%
Other	(109)	(4.8)%	—	—%	(193)	(3.1)%	(8)	(0.1)%
Loss before income tax provision	(1,575)	(68.6)%	(3,531)	(164.0)%	(5,335)	(86.1)%	(9,668)	(144.4)%
Income tax expense	6	0.3%	3	0.1%	34	0.5%	21	0.3%
Net loss	$(1,581)	(68.9)%	$(3,534)	(164.0)%	$(5,369)	(86.6)%	$ (9,689)	(144.7)%

Non-GAAP Disclosures

In addition to the financial information prepared in conformity with GAAP, we provide certain historical non-GAAP financial information. Management believes that these non-GAAP financial measures assist investors in making comparisons of period-to-period operating results.

Management believes that the presentation of this non-GAAP financial information provides investors with greater transparency and facilitates comparison of operating results across a broad spectrum of companies with varying capital structures, compensation strategies, and amortization methods, which provides a more complete understanding of our financial performance, competitive position, and prospects for the future. However, the non-GAAP financial measures presented herein have certain limitations in that they do not reflect all of the costs associated with the operations of our business as determined in accordance with GAAP. Therefore, investors should consider non-GAAP financial measures in addition to, and not a substitute for, or as superior to, measures of financial performance prepared in accordance with GAAP. Further, the non-GAAP financial measures presented by the Company may be different from similarly named non- GAAP financial measures used by other companies.

Adjusted EBITDA

Management uses adjusted EBITDA in its evaluation of the Company's core results of operations and trends between fiscal periods and believes that these measures are important components of its internal performance measurement process. Adjusted EBITDA is defined as net loss before interest, taxes, depreciation and amortization, stock-based compensation, changes in fair value of liability warrants, and other one- time costs.

The following table contains a reconciliation of GAAP net loss to Adjusted EBITDA attributable to common stockholders for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP net loss	$(1,581)	$(3,534)	$(5,369)	$ (9,689)
Adjustments:				
Interest (income) expense, net	—	(5)	(13)	(9)
Income tax expense (benefit)	6	3	34	21
Depreciation and amortization	6	50	17	147
Stock-based compensation expense	32	216	169	656
Gain on disposal of assets, net	—	—	—	(33)
Impairment of long-lived assets	—	777	—	777
Gain on changes in fair value of liability warrants	(27)	(412)	(46)	(3,850)
Gain on extinguishment of debt	—	—	(429)	—
Adjusted EBITDA	$(1,564)	$(2,905)	$(5,637)	$(11,980)

Comparison of Results of Operations

Three months ended September 30, 2024 and September 30, 2023

Revenue. The following table summarizes our unaudited revenue by geographic location based on the location of customers for the three months ended September 30, 2024 and 2023, as well as the percentage of each location to total revenue and the amount of change and percentage of change (dollars in thousands):

	Three Months Ended September 30,				Amount Change	Percentage Change
	2024		2023			
United States	$2,009	87.7%	$1,732	80.4%	$277	16.0%
Australia	111	4.8%	139	6.5%	(28)	(20.1)%
Europe	168	7.3%	258	12.0%	(90)	(34.9)%
Rest of World	4	0.2%	26	1.1%	(22)	(84.6)%
Total revenue	$2,292	100.0%	$2,155	100.0%	$137	6.4%

Revenue totaled $2.3 million for the three months ended September 30, 2024, which represents an increase of 6.4%, or $0.1 million compared to the same period in 2023. This primarily resulted from a small increase in sales volume offset by continued pressure primarily from GLP-1 pharmaceutical weight-loss alternatives.

Cost of Goods Sold and Gross Profit. The following table summarizes our unaudited cost of revenue and gross profit for the three months ended September 30, 2024 and 2023, as well as the percentage compared to total revenue and amount of change and percentage of change (dollars in thousands):

	Three Months Ended September 30,				Amount Change	Percentage Change
	2024		2023			
Revenue	$2,292	100.0%	$2,155	100.0%	$137	6.4%
Cost of revenue	853	37.2%	867	40.2%	(14)	(1.6)%
Gross profit	$1,439	62.8%	$1,288	59.8%	$151	11.7%

Gross Profit. Gross profit for the three months ended September 30, 2024, was $1.4 million, which was slightly above $1.3 million for the same period in 2023. Gross profit as a percentage of total revenue for the three months ended September 30, 2024, was 62.8% compared to 59.8% for the same period in 2023. The increase in gross profit percentage is due to the reduction in overhead related costs, primarily payroll, as we had a reduction of employees late in 2023.

Operating Expense. The following table summarizes our unaudited operating expenses for the three months ended September 30, 2024 and 2023, as well as the percentage of total revenue and the amount of change and percentage of change (dollars in thousands):

	Three Months Ended September 30,				Amount Change	Percentage Change
	2024		2023			
Sales and marketing	$ 719	31.4%	$1,791	83.1%	$(1,072)	(59.9)%
General and administrative	2,082	90.8%	2,058	95.5%	24	1.2%
Research and development	399	17.4%	542	25.2%	(143)	(26.4)%
Impairment of long-lived assets	—	—%	777	36.1%	(777)	(100.0)%
Total operating expenses	$3,200	139.6%	$5,168	239.9%	$(1,968)	(38.1)%

Sales and Marketing Expense. Sales and marketing expenses for the three months ended September 30, 2024, decreased by $1.1 million, or 59.9%, to $0.7 million, compared to $1.8 million for the same period in 2023. The decrease is primarily due to a decrease of $0.5 million in advertising and marketing expenses, including consulting and professional marketing services, as the Company has reevaluated its marketing approach and has moved to a targeted digital marketing campaign, resulting in a reduction of costs. Additionally, there was a decrease of $0.5 million in payroll-related expenditures, including commissions, stock compensation expense and travel, due to changes in sales personnel and a reduction in sales, and a reduction of $0.1 million in other expenses.

General and Administrative Expense. General and administrative expenses for the three months ended September 30, 2024, increased by $24 thousand, or 1.2%, to approximately $2.1 million, compared to $2.1 million for the same period in 2023. The increase is primarily due a $0.4 million increase in professional

services primarily related to the merger and asset sale transaction that was entered into during July 2024, offset by a $0.2 million reduction in employee related expenses, $0.1 million in bad debt expense, and $0.1 million in other expenses.

Research and Development Expense. Research and development expenses for the three months ended September 30, 2024, decreased by $0.1 million, or 26.4% to $0.4 million, compared to the same period in the prior year. The primary reason for the decrease is due to a reduction in payroll, consulting and clinical trials, as the Company has paused all clinical work to preserve cash.

Impairment of Long-Lived Assets. Impairment of long-lived assets decreased by $0.8 million for the three months ended September 30, 2024, compared to the same period in the prior year. During the three months ended September 30, 2023, the Company impaired approximately $0.8 million, consisting of fixed assets and intangible assets. During the three months ended September 30, 2024, no impairment was recorded.

Nine months ended September 30, 2024 and September 30, 2023

Revenue. The following table summarizes our unaudited revenue by geographic location based on the location of customers for the nine months ended September 30, 2024 and 2023, as well as the percentage of each location to total revenue and the amount of change and percentage of change (dollars in thousands):

	Nine Months Ended September 30,				Amount Change	Percentage Change
	2024		2023			
United States	$5,290	85.3%	$5,473	81.7%	$(183)	(3.3)%
Australia	316	5.1%	419	6.3%	(103)	(24.6)%
Europe	564	9.1%	756	11.3%	(192)	(25.4)%
Rest of world	31	0.5%	48	0.7%	(17)	(35.4)%
Total revenue	$6,201	100.0%	$6,696	100.0%	$(495)	(7.4)%

Revenue totaled $6.2 million for the nine months ended September 30, 2024, which represents a contraction of 7.4%, or $0.5 million compared to the same period in 2023. This primarily resulted from a decrease in sales volume primarily due to GLP-1 pharmaceutical weight-loss alternatives.

Cost of Goods Sold and Gross Profit. The following table summarizes our unaudited cost of revenue and gross profit for the nine months ended September 30, 2024 and 2023, as well as the percentage compared to total revenue and amount of change and percentage of change (dollars in thousands):

	Nine Months Ended September 30,				Amount Change	Percentage Change
	2024		2023			
Revenue	$6,201	100.0%	$6,696	100.0%	$(495)	(7.4)%
Cost of revenue	2,463	39.7%	2,990	44.7%	(527)	(17.6)%
Gross profit	$3,738	60.3%	$3,706	55.3%	$ 32	0.9%

Gross Profit. Gross profit for both the nine months ended September 30, 2024 and 2023, was $3.7 million, respectively. Gross profit as a percentage of total revenue for the nine months ended September 30, 2024, was 60.3% compared to 55.3% for the same period in 2023. The increase in gross profit percentage is due to the reduction in overhead related costs, primarily payroll, as we had a reduction of employees late in 2023.

Operating Expense. The following table summarizes our unaudited operating expenses for the nine months ended September 30, 2024 and 2023, as well as the percentage of total revenue and the amount of change and percentage of change (dollars in thousands):

	Nine Months Ended September 30,				Amount Change	Percentage Change
	2024		2023			
Sales and marketing	$2,408	38.8%	$ 6,150	91.8%	$(3,742)	(60.8)%
General and administrative	6,074	98.0%	8,724	130.3%	(2,650)	(30.4)%
Research and development	1,282	20.7%	1,576	23.5%	(294)	(18.7)%
Impairment of long-lived assets	—	—%	777	11.6%	(777)	(100.0)%
Gain on disposal of assets, net	—	—%	(33)	(0.5)%	33	(100.0)%
Total operating expenses	$9,764	157.5%	$17,194	256.8%	$(7,430)	(43.2)%

Sales and Marketing Expense. Sales and marketing expenses for the nine months ended September 30, 2024, decreased by $3.7 million, or 60.8%, to $2.4 million, compared to $6.2 million for the same period in 2023. The decrease is primarily due to a decrease of approximately $2.0 million in advertising and marketing expenses, including consulting and professional marketing services, as the Company has reevaluated its marketing approach and has moved to a targeted digital marketing campaign, resulting in a reduction of costs. Additionally, there was a decrease of $1.6 million in payroll-related expenditures, including commissions, stock compensation expense and travel, due to changes in sales personnel and a reduction in sales, and a $0.1 million reduction in other expenses.

General and Administrative Expense. General and administrative expenses for the nine months ended September 30, 2024, decreased by $2.7 million, or 30.4%, to $6.1 million, compared to $8.7 million for the same period in 2023. The decrease is primarily due to a reduction in professional services, such as audit and legal fees of $1.1 million primarily due to the Company incurring one-time adjustments for professional services related to the February 2023 public offering, and a reduction in payroll-related expenditures, including stock-based compensation expense, of $1.0 million due to decline in staffing levels, and a reduction in rent expense of $0.1 million, as we moved our headquarters at the end of the second quarter of 2023 to a smaller facility to reduce costs. Additionally, there was a reduction in bad debt expense of $0.4 million, and a reduction in other miscellaneous expenses of $0.1 million.

Research and Development Expense. Research and development expenses for the nine months ended September 30, 2024, decreased by $0.3 million, or 18.7% to $1.3 million, compared to approximately $1.6 million for the same period in the prior year. The primary reason for the decrease is due to a reduction in consulting and clinical trials, as the Company has paused all clinical work to preserve cash.

Impairment of Long-Lived Assets. Impairment of long-lived assets decreased by $0.8 million for the nine months ended September 30, 2024, compared to the same period in the prior year. During the nine months ended September 30, 2023, the Company impaired approximately $0.8 million, consisting of fixed assets and intangible assets. During the nine months ended September 30, 2024, no impairment was recorded.

Gain loss on disposal of assets, net. During the nine months ended September 30, 2023, the Company had a gain of approximately $33 thousand related to the sale of fully depreciated assets. During the nine months ended September 30, 2024, no disposals were recorded.

Liquidity and Capital Resources

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company currently does not generate revenue sufficient to offset operating costs and anticipates such shortfalls to continue as the Company has modified its strategy to a metrics-driven approach through a sustainable and scalable business model, via a digital lead generation and re-engagement strategy. As of September 30, 2024, the Company had net working capital of approximately $1.3 million, primarily due to cash and cash equivalents and restricted cash of $0.8 million. The Company's principal source of liquidity as of September 30, 2024, consisted of approximately $0.8 million of cash and cash equivalents and restricted cash, and $1.3 million of accounts receivable. Additionally, the Company has raised gross proceeds of $0.7 million from the issuance of a senior secured convertible note on October 16, 2024. Based on its available cash resources, the Company will not have sufficient cash on hand to fund its current operations for more than twelve months from the date of this filing. This condition raises

substantial doubt about the Company's ability to continue as a going concern. The Company believes in the viability of its business strategy, which includes a merger and asset sale, and in its ability to raise additional funds, however, there can be no assurance to that effect. Management's plans are assuming the merger with Vyome and the asset purchase with Biorad, announced in July of 2024 occur.

The following table summarizes our change in cash and cash equivalents and restricted cash (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	$(3,740)	$(14,503)
Net cash used in investing activates	—	(10)
Net cash provided by financing activities	24	12,113
Effect of exchange rate changes	—	(6)
Net change in cash and cash equivalents and restricted cash	$(3,716)	$ (2,406)

Net Cash Used in Operating Activities

Net cash used in operating activities from operations was $3.7 million and $14.5 million for the nine months ended September 30, 2024 and 2023, respectively. For the nine months ended September 30, 2024, net cash used in operating activities was primarily the result of our net loss of $5.4 million, partially offset by non-cash adjustments for stock-based compensation expense of $0.2 million and inventory reserve of $0.1 million, offset by a negative cash impact of $0.4 million related to old accounts payable that have passed their statute of limitations. We show a positive cash impact on accounts payable of $0.7 million, inventory of approximately $0.7 million, accounts receivable of $0.3 million, and prepaid expenses of $0.1 million.

For the nine months ended September 30, 2023, net cash used in operating activities was primarily the result of our net loss of $9.7 million, partially offset by non-cash adjustments for stock-based compensation expense of $0.7 million, non-cash offering cost of $0.3 million and bad debt expense of approximately $0.5 million, offset by a negative cash impact related to gains recognized for changes in fair value of liability warrants of $3.9 million. We show a negative cash impact on accounts payable and accrued liabilities of $2.8 million, accounts receivable of $0.4 million, and prepaid expenses of $0.3 million. This was offset by a positive cash impact on inventory of $0.3 million.

Net Cash Used in Investing Activities

There was no cash used in investing activities for the nine months ended September 30, 2024, and net cash used in investing activities for the nine months ended September 30, 2023, was minimal.

Net Cash Provided by Financing Activities

Financing activities provided $24 thousand related to exercise of warrants for the nine months ended September 30, 2024. Net cash provided by financing activities was $12.1 million for the nine months ended September 30, 2023, due to the proceeds received from the public offering completed during February 2023 and April 2023, less costs to complete the transaction and costs paid related to the October 2023 offering.

Operating Capital and Capital Expenditure Requirements

The Company's anticipated operations include plans to (i) merge with Vyome Therapeutics, Inc and sell certain assets to Biorad, which will continue the operations, (ii) grow sales and operations of the Company with the Lap-Band product line both domestically and internationally as well as to obtain cost savings synergies, (iii) introduce to the market Lap-Band 2.0 FLEX, (iv) continue development of the Diabetes Bloc- Stim Neuromodulation ("DBSN") device, and (v) prior to such merger, explore and capitalize on synergistic opportunities to expand our portfolio and offer future minimally invasive treatments and therapies in the obesity continuum of care. The Company believes that it has the flexibility to manage the growth of its

expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing and product development activities. If management's plans do not develop, and the Company does not raise additional cash in addition to the funds raised in October 2024, at the current burn rate, management expects to run out of cash during the fourth quarter of 2024.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our Diabetes Bloc-Stim Neuromodulation, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of the Diabetes Bloc-Stim Neuromodulation or other additional products and successfully deliver a commercial product to the market. Future capital requirements will depend on many factors and will be decided by Biorad, once the pending asset sale is complete.

Critical Accounting Policies and Estimates

The condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States which require us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the condensed consolidated financial statements and revenues and expenses during the periods reported. Actual results could differ from those estimates. Information with respect to our critical accounting policies and estimates which we believe could have the most significant effect on our reported results and require subjective or complex judgments by management is contained in Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," of our Annual Report on Form 10-K for the year ended December 31, 2023. There have been no significant changes from the information discussed therein.

During the nine months ended September 30, 2024, there were no material changes to our significant accounting policies, which are fully described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023.

BUSINESS

Our Company

ReShape Lifesciences Inc. is a premier physician-led weight-loss solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease throughout the care continuum.

Our current portfolio includes the FDA-approved and reimbursed Lap-Band® system, which provides minimally invasive, long-term treatment of obesity and is a safer surgical alternative to more invasive and extreme surgical stapling procedures such as the gastric bypass or sleeve gastrectomy.



ReShape's Pillars for Growth

In August of 2022, Paul F. Hickey joined ReShape as President and Chief Executive Officer. Under this new leadership, the Company has pivoted its business strategy with the intent of helping to ensure growth and profitability. The Company has executed the following three growth strategies, or pillars for growth:

- **Growth Pillar I: Executing disciplined, metrics-driven business operations.**

In executing the first growth pillar, the Company is focused on revenue growth and profitability. This first growth pillar remains, in the Company's opinion, paramount for ReShape to deliver shareholder value and, ultimately, profitability. Starting shortly after Mr. Hickey's appointment, ReShape has made several operational changes to help ensure future performance and return on investment by prioritizing investments supporting revenue growth.

The Company is prioritizing investments, including marketing automation to support scalable lead acquisition, segmented consumer-centric messaging via an updated website for improved patient engagement, and a frictionless booking system with qualified providers. This is expected to dramatically increase Lap-Band procedures and ultimately revenue. Additionally, the Company has a 2024 cost reduction plan, which is expected to result in reduction of operating expense by approximately 55.4% from 2023, excluding one-time costs. The company has also taken steps to right-size the organization in several areas to ensure sustainability and scalability.

- **Growth Pillar II: Expanding the product portfolio and future product pipeline.**

ReShape's second growth pillar is intended to further differentiate the Company as a leading provider of innovative products and services to meet unmet customer needs. ReShape is committed to drive and scale

its new product development and commercialization capacity, providing a cadence of new product introductions and revenue growth. The growth can either be through organic internal Research and Development efforts, or through strategic partnerships, mergers, or acquisitions. Key growth drivers within second growth pillar include:

Lap-Band 2.0 FLEX System — New product revenues for the Lap-Band 2.0 FLEX system ("Lap-Band 2.0"), for which the Company received FDA approval during December 2023 and completed the first successful surgeries in early 2024. Similar to the current Lap-Band, the Lap-Band 2.0 is adjustable, postoperatively, to increase or decrease the opening of the band to optimize an individual's eating habits and comfort, thereby improving therapy effectiveness. At the same time, a new feature of the Lap-Band 2.0 is a band reservoir technology that serves as a relief valve. Pieces of food that are too large to pass through the narrowed passage, created by the current band, can pass through because the new feature allows the band to relax momentarily and then return to its resting diameter. This could potentially allow for increased Lap-Band constriction and resultant satiety, while helping to minimize discomfort from swallowing large pieces of food, which may otherwise require emergency in-office patient band adjustments. Based on customer feedback, Lap-Band 2.0 will allow us to engage new surgeons and reengage many of those who have used the Lap-Band, historically.

ReShape Obalon Balloon — The ReShape Obalon® Balloon system is the first and only swallowable, gas filled, FDA-approved balloon system. In 2023 the Company established an OEM partnership with Biorad Medisys ("Biorad"), based in India that will support the successful relaunch and commercialization of the balloon system. We anticipate having access to the Obalon Balloon system later in 2024 for the distribution in the U.S. and other regions globally. In addition, the strategic partnership with Biorad contemplates potential manufacturing transfer of other products to further improve ReShape's overall gross margin.

DBSN Device — ReShape remains committed to furthering our proprietary Diabetes Bloc-Stim Neuromodulation (DBSN™) technology that can potentially reduce the dependence on medications by those with type 2 diabetes. The DBSN™ device is a technology under development as a new treatment for type 2 diabetes mellitus. The device is expected to use bioelectronics to manage blood glucose in the treatment of diabetes and individualized 24/7 glucose control. Preclinical evidence on the DBSN device was presented at multiple conferences. The DBSN technology development has received nondilutive NIH grant support.

- **Growth Pillar III: Ensuring that our portfolio spans the weight loss care continuum and is evidence based.**

ReShape's third growth pillar represents the Company's commitment to collaborate with healthcare professionals worldwide and further develop evidence supporting ReShape's portfolio of treatment options. Aligned with goal of pillar three, in early 2023, ReShape established their first-ever global Scientific Advisory Board (SAB) to provide needed expertise and feedback on initiatives related to the Company's growth pillars. The SAB is fully engaged in helping validate company strategies to collect and publish data on both our Lap-Band 2.0 and data on Lap-Band patients who are also using GLP-1s as a combination therapy. Combination therapies comprising GLP-1s and other gastric surgeries, including the Lap-Band, are being prescribed today, to help those who have plateaued with their weight loss.

Our Product Portfolio

Lap-Band System

The Lap-Band System is designed to provide minimally invasive long-term treatment of severe obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. Unlike other invasive anatomy altering procedures, the Lap-Band System is adjustable post-operatively via a saline-filled silicone band that is laparoscopically placed around the upper part of the stomach through small laparoscopic incisions, creating a small pouch at the top of the stomach, which slows the passage of food and creates a sensation of fullness. The procedure can normally be performed as an outpatient procedure and patients can go home the day of the procedure without the need for an overnight hospital stay.

Lap-Band 2.0 System

The Lap-Band 2.0, like the original Lap-Band System, is designed to provide minimally invasive long-term treatment of severe obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. Unlike more invasive and anatomy altering surgeries, the Lap-Band 2.0 is adjustable postoperatively to increase or decrease the pressure to the band in order to optimize an individual's comfort and therapy effectiveness. The Lap-Band 2.0 system includes a reservoir technology designed to minimize postoperative in-office patient band adjustments, thereby potentially improving an individual's tolerance for the Lap-Band 2.0.

ReShape Calibration Tubes

The ReShape Calibration tubes are multifunctional devices compared to reusable bougies and disposable gastric tubes. The Calibration tubes are designed to fit the lesser curvature of the stomach more easily and quickly reach the pylorus. In August of 2022, we announced FDA clearance of three new sizes — 32, 36, and 40 French — all designed to simplify bariatric procedures such as laparoscopic sleeve gastrectomy, gastric bypass, and adjustable gastric banding. During the first quarter of 2023, we fully released this product and continue to ramp up production.

ReShape Obalon Balloon System

The FDA PMA approved Obalon Balloon System, is not currently manufactured and distributed for commercial sales, consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Obalon Navigation System console, has FDA PMA supplemental approval, is a combination of hardware and software used to dynamically track and display the location of the balloon during placement; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas.

DBSN Device

The DBSN device, that is not currently available for commercial sales, is a technology under development as a new treatment for type 2 diabetes mellitus (T2DM). It combines ReShape Lifesciences' proprietary Vagus Nerve Block (vBloc) technology platform in combination with Vagus nerve stimulation. This new dual Vagus nerve neuromodulation device selectively modulates vagal blocking and stimulation to the liver and pancreas to manage blood glucose. Our DBSN device is expected to use bioelectronics to manage blood glucose in treatment of diabetes and individualized 24/7 glucose control. The goal is to reduce costs of treatment and complications that arise from poorly controlled blood glucose and non-compliance to T2DM medication.

Our Strategic Focus

Develop and Commercialize a Differentiated Portfolio of Products/Therapies

ReShape Lifesciences Inc. is the premier physician-led weight-loss and metabolic health-solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease. An overarching strategy for our Company is to develop and commercialize products, programs and services portfolio that is differentiated from our competition by offering transformative technologies that consists of a selection of patient-friendly, non-anatomy changing, lifestyle enhancing products, programs and services that provide alternatives to more invasive bariatric surgeries, and help patients achieve healthy and durable weight loss. Current offerings include the Lap-Band System and accessories, and recently approved Lap-Band 2.0. The FDA approved Obalon Balloon System, which has been off the market since March 2020 and was acquired in connection with the Obalon merger in June of 2021, has not yet been re-introduced to the marketplace. We believe that we are well positioned for the existing market and can serve more of the overweight and obese population with our solutions and thereby help expand the addressable market for obesity.

Drive the Adoption of Our Portfolio through Obesity Therapy Experts and Patient Ambassadors

Our clinical development strategy is to collaborate closely with regulatory bodies, healthcare providers, obesity therapy lifestyle experts and others involved in the obesity management process, patients and their advocates and scientific experts. We have established relationships with physicians, obesity therapy experts, patient advocates, media experts and other market drivers we believe will provide important support towards promoting patient awareness and gaining widespread adoption of the Lap-Band, its accessories, Lap-Band 2.0 and the possible re-introduction of the Obalon Balloon System.

Expand and Protect Our Intellectual Property Position

We believe that our issued patents and our patent applications encompass a broad platform of therapies focused on obesity, diabetes, hypertension and other gastrointestinal disorders. We intend to continue to pursue further intellectual property protection through U.S. and foreign patent applications.

On March 9, 2023, we filed a patent infringement complaint against Allurion Technologies, Inc. in the U.S. District Court for the District of Delaware. The complaint alleged that Allurion is infringing at least two claims of our U.S. Patent No. 10,463,520, which is related to our intellectual property portfolio, by making the Allurion Gastric Balloon system in the U.S. for exportation and/or sales from the U.S and/or for potential sales in the U.S. relating to Allurion's application to the FDA to sell the Allurion Gastric Balloon in the U.S. The complaint sought, among other relief, damages for Allurion's alleged infringement of the '520 patent, in an amount not less than a reasonable royalty. On May 31, 2023, we filed a voluntary dismissal, without prejudice, of the complaint, which reserves our right to assert the claim against Allurion. Since that time, in October 2023, we have been issued another patent, U.S. Patent No. 11,779,482, which arises out of the same family as the '520 patent, and also applies to the Allurion Gastric Balloon system. We are also pursuing a third patent out of the same family, which we expect to be issued soon. This matter is in its early stages and we are unable to predict its outcome at this time. However, we intend to continue to vigorously protect and enforce our intellectual property rights.

Our Market

The Obesity and Metabolic Disease Epidemic

Obesity is a disease that has been increasing at an alarming rate with significant medical repercussions and associated economic costs. The World Health Organization ("WHO") currently estimates that more than 2.5 billion adults, approximately 30% of the global population, are considered overweight or obese. This number has a projected increase to 50% by 2030. The global economic impact of obesity is approximately $2.0 trillion, or approximately 2.8% of global GDP. Healthcare costs for severely or morbidly obese adults are 81% higher than for healthy weight adults and obesity is responsible for 5% of deaths worldwide. We believe our products and programs and product candidates could address a $1.64 billion per year and growing global surgical device market. The Bariatric Surgical Device market is projected to be a $2.8 billion worldwide market ($1.8 billion in the U.S.) by 2025, the Virtual Healthcare Delivery market is projected to be $95 billion worldwide by 2026, and the Global Weight Loss and Obesity Management market is expected to rise to an estimated value of $300 billion with a compound annual growth rate of 6.7% from 2019 to 2026.

We believe that this epidemic will continue to grow worldwide given dietary trends in developed nations that favor highly processed sugars, larger meals and fattier foods, as well as increasingly sedentary lifestyles. Despite the growing obesity rate, increasing public interest in the obesity epidemic and significant medical repercussions and economic costs associated with obesity, there continues to be a significant unmet need for effective treatments.

The United States Market

Obesity has been identified by the U.S. Surgeon General as the fastest growing cause of disease and death in the United States. Currently, it is estimated that approximately 160 million American adults are overweight or obese, 74 million American adults are overweight, 78 million American adults are obese or severely obese, and 24 million American adults are morbidly obese. It is estimated that if obesity rates stay

consistent, 51% of the U.S. population will be obese by 2030. According to data from the U.S. Department of Health and Human Services, almost 80% of adults with a BMI above 30 have comorbidity, and almost 40% have two or more of these comorbidities. According to The Obesity Society and the CDC, obesity is associated with many significant weight-related comorbidities including Type 2 diabetes, high blood-pressure, sleep apnea, certain cancers, high cholesterol, coronary artery disease, osteoarthritis and stroke. According to the American Cancer Society, 572,000 Americans die of cancer each year, over one-third of which are linked to excess body weight, poor nutrition and/or physical inactivity. Over 75% of hypertension cases are directly linked to obesity, and more than 90% of the approximately 28 million U.S. adults with Type 2 diabetes are overweight or have obesity.

Currently, medical costs associated with obesity in the U.S. are estimated to be up to $210.0 billion per year and nearly 21% of medical costs in the U.S. can be attributed to obesity. Approximately $1.5 billion was spent in 2015 alone in the U.S. on approximately 200,000 bariatric surgical procedures to treat obesity. By 2025, it is estimated that up to $3.8 billion will be spent in the U.S. on approximately 800,000 bariatric surgical procedures to treat obesity. Researchers estimate that if obesity trends continue, obesity-related medical costs could rise by another $44-$66 billion each year in the U.S. by 2030. The medical costs paid by third-party payers for people who are obese were $2,741 per year, or 42% higher than those of people who are normal weight and the average cost to employers is $6,627 to $8,067 per year per obese employee (BMI of 35 to 40 and higher).

Current Treatment Options and Their Limitations

We believe existing bariatric surgery and endoscopic procedural options for the treatment of obesity have seen limited adoption to date, with approximately 1% of the obese population qualifying for treatment actually seeking treatment, due to patient concerns and potential side effects including permanently altered anatomy and morbidity. The recent adoption surge of GLP-1 agonists for weight loss and related big-pharma marketing efforts have significantly increased the number of overweight and obese individuals who are seeking medically managed weight loss.

The principal treatment alternatives available today for obesity include:

- **Behavioral modification.** Behavioral modification, which includes diet and exercise, is an important component in the treatment of obesity; however, most obese patients find it difficult to achieve and maintain significant weight loss with a regimen of diet and exercise alone.
- **Pharmaceutical therapy.** Pharmaceutical therapies often represent a first option in the treatment of obese patients but carry significant safety risks and may present troublesome side effects and compliance issues.
- **Bariatric Surgery and Endoscopic Procedures.** In more severe cases of obesity, patients may pursue more aggressive surgical treatment options such as sleeve gastrectomy and gastric bypass. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size. While largely effective, these procedures generally result in major lifestyle changes, including dietary restrictions and food intolerances, and they may present substantial side effects and carry short- and long-term safety and side effect risks that have limited their adoption.

Given the limitations of behavioral modification, the inaccessibility, side-effects, and durability of pharmaceutical therapy, and the invasive and irreversible nature of other bariatric surgical approaches, we believe that there is a substantial need for the less invasive, adjustable, and reversable Lab-Band.

Our Competition

The market for obesity treatments is competitive, subject to technological change and significantly affected by new product development. Our primary competition in the obesity treatment market is currently from bariatric laparoscopic and endoscopic procedures, and the recently introduced GLP-1 pharmaceuticals.

Our Lap-Band System competes, and we expect that our Obalon Balloon System may compete, with surgical and endoscopic obesity procedures, including gastric bypass, gastric balloons, sleeve gastrectomy and the endoscopic sleeve. These current surgical procedures are performed in less than 1% of all eligible obese

patients today. Outside of the Obalon Balloon System which we recently acquired, other current manufacturers of gastric balloon and suturing products that are approved in the United States include Boston Scientific (ORBERA Intragastric Balloon System and OverStitch Endoscopic Suturing System) and Spatz Medical.

In June 2016, Aspire Bariatrics, Inc. received FDA approval for the Aspire Assist® System, an endoscopic alternative to weight loss surgery for people with moderate to severe obesity. Due to the financial impact of the COVID-19 pandemic, Aspire Bariatrics shut down operations and withdrew its product from the market in April 2022. We are also aware that GI Dynamics, Inc. has received approvals in various international countries to sell its EndoBarrier Gastrointestinal Liner.

We also compete against the manufacturers of pharmaceuticals that are directed at treating obesity and the 99% of obese patients eligible for surgery that are not willing to pursue a surgical option. We are aware of a number of drugs that are approved for long-term treatment of obesity in the United States: Orlistat, marketed by Roche as Xenical and GlaxoSmithKline as Alli, Belviq marketed by Arena Pharmaceuticals, Inc., Qsymia, marketed by VIVUS, Inc.,Contrave, marketed by Orexigen Therapeutics, Inc. Wogovy/Ozempic marketed by Novo Nordisk. While considered a competitive therapy, we expect that the marketing of these pharmaceuticals will increase awareness and help normalize obesity treatment. Further, we some surgeons will use pharmaceuticals to coincide with a Lap-Band placement.

In addition to competition from surgical obesity procedures, we compete with several private early-stage companies developing neurostimulation devices for application to the gastric region and related nerves for the treatment of obesity. Further, we know of two intragastric balloon companies in the U.S., Spatz Medical, which received FDA approval of the Spatz3 Adjustable Balloon in October of 2021, and Allurion Technology's Elipse Balloon, which is in either clinical trials or working toward clinical trials in the U.S. These companies may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. They also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We believe that the principal competitive factors in our market include:

- acceptance by healthcare professionals, patients and payers;
- published rates of safety and efficacy;
- reliability and high-quality performance;
- effectiveness at controlling and/or resolving comorbidities such as diabetes and hypertension;
- invasiveness and the inherent reversibility of the procedure or device;
- cost and average selling price of products and relative rates of reimbursement;
- effective marketing, training, education, sales and distribution;
- regulatory and reimbursement expertise;
- technological leadership and superiority;
- speed of product innovation and time to market.

Many of our competitors are larger than we are, and they may enjoy several competitive advantages over us, including:

- stronger name recognition;
- existing relations with healthcare professionals, customers and third-party payers;
- established distribution networks;
- significant experience in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals, obtaining reimbursement and marketing approved products; and

- greater financial and human resources.

As a result, we cannot assure you that we will be able to compete effectively against these companies or their products.

Market Opportunity

Given the limitations of behavioral modification, pharmaceutical therapy and traditional bariatric surgical approaches, we believe there is a substantial need for patient-friendly, safer, effective and durable solutions that:

- provide proven, long-term weight loss;
- preserve normal anatomy;
- are adjustable in an office setting for individual patient needs and long term efficacy;
- are "non-punitive" in that they support continued ingestion and digestion of foods and micronutrients such as vitamins and minerals found in a typical, healthy diet while allowing the user to modify his or her eating behavior appropriately without inducing punitive physical restrictions that physically force a limitation of food intake;
- diminish undesirable side-effects;
- facilitate outpatient surgical procedures;
- minimize the risks of re-operations, malnutrition and mortality;
- reduce the natural hunger drive of patients; and
- are reversible, if necessary or desired, while preserving anatomy.

Our Intellectual Property

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that does not infringe our patents. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

Lap-Band

As of December 31, 2023, we had approximately 50 total patents, 28 U.S. and 22 foreign, related to our Lap-Band System. The international patents and patent applications are in regions including Germany, France, Spain, the United Kingdom, Mexico, Canada, Italy, the Netherlands, Portugal, Ireland, Belgium, Poland, Australia, and South Korea. The issued patents expire between the years 2023 and 2031.

We also have 48 total U.S. and international trademarks for the Lap-Band brand name.

ReShape Vest

As of December 31, 2023, we had four granted U.S. patents and four granted foreign patents in China, Israel, Canada and Australia related to our ReShape Vest. The patents expire between the years 2028 and 2038.

We also have U.S. and international trademark applications for the ReShape Vest brand name.

Obalon

As of December 31, 2023, we had 46 granted U.S. patents and 5 granted foreign patents related to our Obalon portfolio. The patents expire between the years 2028 and 2031.

DBSN Device

As of December 31, 2023, we had 9 U.S. patents issued and 45 foreign patents issued. In addition, we have filed a trademark application for Bloc-Stim Neuromodulation. The USPTO Examiner is reviewing the application and provided the Company with a disclaimer being required for "Neuromodulation", as this a standard requirement for words that are in the standard vernacular.

Sales and Distribution

We market directly to patients but sell the Lap-Band program to select qualified surgical centers throughout the U.S. and internationally having patients that would like to treat obesity and its comorbidities. The centers then perform the Lap-Band procedure and are most-commonly reimbursed by leading insurance providers in the U.S. and government health services in many areas outside the U.S. Alternatively, surgical centers can offer the Lap-Band as a cash-pay procedure. Our sales representatives are supported by field-based experts who provide training, technical support, and other support services at various medical centers. Our sales representatives help implement consumer marketing programs and provide surgical centers and certified surgeons with educational patient materials.

In August of 2022, we shifted away from national advertising campaign initiatives and focusing on digital marketing channels including search engine ads and social media channels. This shift in marketing is 100% aligned with the Company's focus on expanding Lap-Band use while ensuring a sustainable (profitable) business. The shift to a more targeted and regionalized marketing program allows us to better support interested potential Lap-Band patients while also reducing the overall costs for lead generation programs. This strategy also aligns with our key surgeon Lap-Band programs across the U.S.; surgeons who participate in local co-op marketing and educational initiatives in their communities.

During 2023, our international sales efforts were through a combination of agent and distributor sales channels, with a focus on top Lap-Band customers in Australia, the Middle East, Canada and select countries in Europe.

Our Manufacturers and Suppliers

To date, all of the materials and components for our products, as well as any related outside services, are procured from qualified suppliers and contract manufacturers in accordance with our proprietary specifications. All of our key manufacturers and suppliers have experience working with commercial implantable device systems, are ISO certified and are regularly audited by various regulatory agencies including the FDA. Our key manufacturers and suppliers have a demonstrated record of compliance with international regulatory requirements. In July 2021 we announced that we had completed our Lap-Band manufacturing transition from Apollo Endosurgery, Inc. to a Massachusetts-based contract manufacturer.

Given that we rely on third-party manufacturers and suppliers to produce our products, our ability to increase production going forward will depend upon the experience, certification levels and large-scale production capabilities of our suppliers and manufacturers. Qualified suppliers and contract manufacturers have been and will continue to be selected to supply products on a commercial scale according to our proprietary specifications. Our FDA approval process requires us to name and obtain approval for the suppliers of key components of the Lap-Band System.

Many of our parts are custom designed and require custom tooling and, as a result, we may not be able to quickly qualify and establish additional or replacement suppliers for the components of our products. Any new approvals of vendors required by the FDA or other regulatory agencies in other international markets for our products as a result of the need to qualify or obtain alternate vendors for any of our components would delay our ability to sell and market our products and could have a material adverse effect on our business.

We believe that our current manufacturing and supply arrangements will be adequate to continue our ongoing commercial sales and our ongoing and planned clinical trials. In order to produce our products in the quantities we anticipate to meet future market demand, we will need our manufacturers and suppliers to increase, or scale up, manufacturing production and supply arrangements by a significant factor over the current level of production. There are technical challenges to scaling up manufacturing capacity and

developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and suppliers and hiring and retaining additional management and technical personnel who have the necessary experience. If our manufacturers or suppliers are unable to do so, we may not be able to meet the requirements to expand the launch of the product in the United States or launch the product internationally or to meet future demand, if at all. We may also represent only a small portion of our suppliers' or manufacturers' business and if they become capacity constrained, they may choose to allocate their available resources to other customers that represent a larger portion of their business. If we are unable to obtain a sufficient supply of our product, our revenue, business and financial prospects would be adversely affected.

Government Regulations

Our products and operations are subject to extensive and rigorous regulation by the FDA and other federal, state and local authorities, as well as foreign regulatory authorities. The FDA regulates, among other things, the research, development, testing, design, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting and import and export of medical devices in the United States to assure the safety and effectiveness of medical products for their intended use. The Federal Trade Commission also regulates the advertising of our products in the United States. Further, we are subject to laws directed at preventing fraud and abuse, which subject our sales and marketing, training and other practices to government scrutiny.

Regulatory system for medical devices in the United States

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FFDCA, also referred to as a 510(k) clearance, or approval from the FDA of a premarket approval ("PMA") application. Both the 510(k) clearance and PMA approval processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Device Classification

Under the FFDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the Quality System Regulations, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the

FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The Investigational Device Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies considered to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed, and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product.

The 510(k) Clearance Process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process. A manufacturer can also submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite PMA application(s).

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- device may not be shown safe or effective to the FDA's satisfaction;
- data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains several conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary,

in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and several devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for several years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer-term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. Our vBloc, Lap-Band System and Intragastric balloons, including the Obalon Balloon System, Obalon Navigation System and Dispenser are considered Class III medical devices. In order to support a PMA application, the FDA required the Company to conduct rigorous and expensive trials, one of which was a double-blinded, randomized, sham-controlled study. We will be required to file new PMA applications or PMA supplement applications for modifications to our PMA-approved Lap-Band System, Obalon Balloon System and Obalon Navigation System and Dispenser or any of their respective components, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

Pervasive and Continuing FDA Regulation

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- The FDA's QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off label uses;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval of product modifications;
- PMA approval of product;
- Medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Since February 2017, the FDA has issued three separate letters to healthcare providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. We are aware of the filing of additional reports of serious adverse events, including deaths, associated with liquid-filled balloons since the issuance of the FDA letters to healthcare providers. While the advisory letters were specific to liquid-filled intragastric balloons and not the Obalon gas-filled balloons, these letters could create negative perceptions of the entire gastric balloon category which may cause negative consequences for us including requiring additional warnings, precautions and/or contraindications in the labeling than originally required, delaying or denying approval of our future products, or possible review or withdrawal of our current approval. Since Obalon Therapeutics began selling in United States in January 2017 — before the merger — Obalon Therapeutics has reported adverse events relating to patient injuries associated with use of the Obalon balloon in the FDA's MAUDE database.

The FDA has broad post-market and regulatory enforcement powers. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures, repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- the FDA's refusal of our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

Regulatory System for Medical Devices in Europe

The European Union ("EU") consists of member states residing in the European Union and has a coordinated system for the authorization of medical devices. As of May 26, 2021, the European Union has adopted Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. The Medical Device Regulation 2017/745, or EU MDR repeals Directive 93/42/EEC, which concerns medical devices, and Directive 90/385/EEC, which concerns active implantable medical devices, as of 26 May 2021. The EU allows a transition period from Directive 93/42/EEC and Directive 90/385/EEC to Regulation (EU) 2017/745, that will end 26 May 2024.

Article 120(3) of the Medical Device Regulation (EU) 2017/745 (MDR), last amended by Regulation (EU) 2023/607, states that devices which continue to comply with the AIMDD or MDD may be placed on the market or put into service until 31 December 2027 for Class IIb implantable (Lap-Band and Obalon Balloon System), or 31 December 2028 for Class IIa devices (ReShape Calibration Tubes, provided the conditions set out in Article 120(3c) MDR are fulfilled. In addition, the "Sell Off" periods have been removed. (Regulation (EU) 2023/607).

These devices are called ‘legacy devices’ and in line with MDCG Guidance Document 2021-253, ‘legacy devices’ should be understood as devices, which, in accordance with the MDR’s transitional provisions, are placed on the market after the MDR’s date of application (i.e. 26 May 2021) if certain conditions are fulfilled. Those devices can be:

- devices which are class I devices under Directive 93/42/EEC (MDD), for which an EC declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;
- devices covered by a valid EC certificate issued in accordance with Directive 90/385/EEC (AIMDD) or the MDD prior to 26 May 2021.

The conditions are set out in Article 120(3c) MDR and include, among others, that legacy devices must continue to comply with the AIMDD/MDD, as applicable, and that there are no significant changes in the design or intended purpose of the device. Therefore, it is important for manufacturers and notified bodies to have a clear understanding as to what changes to design or intended purpose would be considered ‘significant’. It is essential for legacy devices that their certificates remain valid following changes that are not significant with regard to design or intended purpose and that the required appropriate surveillance is carried out.

The EU MDR aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and considering the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

The system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is marked with CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the EUMDR within their jurisdiction. The means for achieving the requirements for CE mark varies according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the requirements to be fulfilled before CE mark can be placed on a product, known as a conformity assessment. Conformity assessments for our products have carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states.

Per MDD 93/42/EEC on Medical Devices, Annex II excluding Section 4, the Lap-Band System is considered a Class IIb device and few of the system’s components are considered Class IIa devices. The vBloc, was never commercialized in the EU. The Obalon Balloon System, when delivered with a cellulose-based capsule was considered a Class IIb product under MDD. Prior to the merger, Obalon Therapeutics’ management believed the Obalon Navigation System and the Obalon Touch Inflation Dispenser are Class I products not requiring Notified Body approval.

ReShape Lifesciences has engaged with its European Notified Body — British Standards Institute (BSI) to transition our products under EU MDR. The Lap-Band and ReShape Calibration Tubes Technical Documentations (TDs) are currently under EU MDR conformity assessment by BSI.

Regulatory frameworks for medical devices in certain countries in Asia Pacific and the Middle East

Australia

ReShape Lifesciences is the legal manufacturer of the Lap-Band System and accessories under the Australian Register of Therapeutic Goods (ARTG), in Australia.

Middle East

Unlike Europe, while the Gulf Cooperation Council, or GCC, jurisdictions often work together to purchase certain medical products in a coordinated fashion for government hospitals, there is not a coordinated system for the authorization of medical devices. Most GCC jurisdictions require that the official registered distributor of a product be wholly owned by nationals of that particular GCC jurisdiction.

ReShape distributes the Lap-Band System and accessories in the Middle East through a distributor. Product is shipped to the Kingdom of Saudi Arabia (KSA) and the United Arab Emirates (UAE).

Obalon Therapeutics ceased distribution of the Obalon System, the Obalon Navigation System and the Obalon Touch Inflation Dispenser in the Middle East prior to the June 16, 2021, merger.

Kingdom of Saudi Arabia, or KSA

The most pertinent regulation is the Interim Regulation for Medical Devices, issued by the Saudi Food & Drug Authority, or SFDA, Board of Directors' Decree number 1-8-1429 dated approximately December 27, 2008, and the implementing regulations of the same. The SFDA is an independent regulatory body that is responsible for the authorization of medical devices, and current guidelines are generally based on pre-existing approval in one of the five founding member nations of the Global Harmonization Task Force, or GHTF, which are Australia, Canada, United States, European Union and Japan. There are no overt requirements for the provision of safety and effectiveness data in the form of clinical trials or other studies, but these would likely come as a part of the approvals described above that are used as a basis to support approval within the KSA. The SFDA reserves its rights to require its own independent clinical trials as it deems necessary or appropriate. Regulatory authorization is required for all medical devices, regardless of device class. A potential exception to this requirement is for medical devices that were designed and constructed by local health care facility and staff for internal use. Similar to the United States, the SFDA requires post market surveillance to ensure safety and quality. This program is meant to be conducted by the Authorized Representative. With respect to the use of medical devices, it is the responsibility of the health care institution to inform the manufacturer and the SFDA of any adverse events associated with this use.

The SFDA has approved the Medical Device Market Authorization, or MDMA application and the listing of ReShape Lifesciences as the legal manufacturer of the Lap-Band System and accessories in KSA.

United Arab Emirates, or UAE

The most pertinent regulation is UAE Federal Law No. 4 of 1983 for the Pharmaceutical Profession and Institutions and to Medical Device Regulations. There are many similarities between the SFDA and the Registration and Drug Control Department that is run out of the Ministry of Health & Prevention of the UAE. Applications for registration of medical devices in the UAE are done with the UAE Ministry of Health Registration & Drug Control Department and must include data on effectiveness in addition to safety (a nod to the requirements of the FDA). The UAE body has its own device classification system that is most closely related to that used by the European Union, defined as class 1, low risk; class 2, medium risk but nonimplantable; class 3, medium risk but implantable; and class 4, high risk.

Brexit

The UK Medicines & Healthcare Products Regulatory Agency, or MHRA is responsible for regulating medical devices in Great Britain. The MHRA plans changes to the UK's Medical Devices Regulations 2002 as part of a broader transition away from European Union legal and regulatory systems.

In addition, the Trade Deal between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

CE Marks issued by EU-recognized notified bodies will continue to be valid in for medical devices placed on the Great Britain market — England, Scotland, and Wales until December 31, 2024. Until that

date, MHRA accepts the CE Marking and requires registering active implantable medical devices, Class III medical devices, Class IIb implantable medical devices and IVD List A devices by May 1, 2021. After December 31, 2024, the UK Conformity Assessment (UKCA) marking will be mandatory. In Northern Island, CE Marking issued by EU-recognized notified bodies will continue to be valid until current CE cert under Medical Device Directive (MDD) expires, after which date, CE marking needs to be approved under EU Medical Device Regulation (EU MDR). ReShape Lifesciences is compliant with the registration requirements and is registered in England, Scotland, Wales, and Northern Ireland. Additionally, the EU no longer recognizes conformity assessment activities performed by UK notified bodies for medical devices placed on the market since January 1, 2021. Notified bodies must be located in a European Union member state, or territory where there is a mutual recognition agreement, or MRA; there is currently no such MRA. The new legislation may create an extra hurdle for manufacturers and thereby limit the availability and/or increase prices of our medical devices in the UK.

The UK government published Statutory Instruments 2023 No. 627, The Medical Devices (Amendment) (Great Britain) Regulations 2023 on June 9, 2023, to extend the deadlines for placing CE Marked devices on the GB market. The date CE Marked devices can be placed on the Great Britain market has been extended to December 31, 2027. After this date the UKCA Mark will be required.

The UK government proposed to adopt the draft Post-Market Surveillance Requirements Statutory Instrument (PMS SI) in December 2023 and to enforce in June 2024. Supplementary guidance will also be published.

Our Products

The ReShape Lifesciences' Lap-Band System, the Obalon Balloon System, Obalon Navigation system and Obalon Touch Inflation Dispenser, and their respective components are medical devices that required a PMA submission form and approval by the FDA for commercial use in the United States. ReShape Lifesciences' vBloc neuromodulation system, which was approved by the FDA for treating obesity is no longer commercialized.

FDA approved the Lap-Band System in 2001. The Lap-Band System was approved for use in the U.S. for patients with a BMI greater than or equal to 40 or a BMI greater than or equal to 30 with one or more obesity-related comorbidity conditions.

The Lap-Band System was CE marked in 1997. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Lap-Band System, the method involved a combination issuance of declaration of conformity by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body of the design of the device and of our quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements. The assessment included, among other things, a clinical evaluation of the conformity of the device with applicable regulatory requirements. We use BSI as the Notified Body for our CE marking approval process.

The Lap-Band 2.0 FLEX system received approval in December 2023. We had our first successful surgeries with this system in early 2024.

Continued compliance with CE marking requirements is enforced through periodic facility inspections by the Notified Body, which may be unannounced. Because we rely on contract manufacturing sites and service providers, these additional sites may also be subject to these Notified Body unannounced inspections.

The Obalon Balloon System was approved in January 2017 and the Obalon Navigation system and Obalon Touch Inflation Dispenser were approved on December 20, 2018. All of the above-listed devices were approved with post-approval conditions intended to ensure the safety and effectiveness of these devices. ReShape Lifesciences assumed and complies with all post market requirements for the Lap-Band System, the Obalon Navigation system, and Obalon Touch Inflation Dispenser.

Obalon Balloon System

Obalon Balloon favorable safety profile, In the pivotal SMART trial, only one of 336 (0.3%) patients that received the Obalon balloon experienced a serious adverse device event (SADE) and in data presented at the American Society for Metabolic and Bariatric Surgery Meeting from the first year of commercial experience, only two of 1,343 (0.14%) patients that received our Obalon balloon experienced a SADE. Historically, the reported rate of SADEs reported to Obalon in commercial use is consistent with that experienced in the pivotal SMART trial or the data from their first year of commercial experience.

In addition, data published and presented from Obalon's commercial registry demonstrates greater weight loss in the commercial setting as compared to the pivotal clinical study used to support FDA approval. In May 2019, Obalon updated data from their commercial registry to include 1,411 total patients from 143 treatment sites in the United States. In this data set, for those patients receiving three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in a 10.2% reduction in total body weight. Of note, 50.7% of patients lost 10% or more total body weight and 77.9% lost 5% or more total body weight.

Obalon Balloon improved patient tolerability and comfort. The Obalon balloon is inflated with a proprietary mix of gas. This creates a light, buoyant balloon that floats at the top of the stomach instead of sinking to the bottom of the stomach like a traditional liquid-filled intragastric balloon. Further, the Obalon Balloon System consists of three separate 250cc balloons placed individually over a three-month period to progressively add volume. We believe these design elements have the potential to improve patient comfort and tolerability of our Obalon balloon.

Obalon Balloon progressive weight loss with durable results. In the pivotal SMART trial, patients in the Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham-control group. In addition, patients in the Obalon treatment group showed, on average, progressive weight loss over the balloon treatment period, which we believe is attributable to the individual placement of three separate Obalon balloons over the treatment period. Subsequent data analysis at 12 months also showed that, on average, 89.5% of the weight loss was maintained six months after balloon removal. In May 2019, Obalon analyzed data from their commercial registry on 1,411 total patients from 143 treatment sites in the United States. In this data set, for those patients receiving three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in a 10.2% reduction in total body weight.

Obalon Balloon simple and convenient placement. The Obalon balloon is placed without anesthesia or an endoscopy through a swallowable capsule that dissolves in the stomach and releases the balloon. These unique features allow patients the flexibility to receive the Obalon balloon discreetly in an outpatient setting. Placement typically occurs in less than fifteen minutes and can be scheduled in the morning before work, during a lunch break or in the evening. Treated patients can return promptly to their normal daily activities. The balloons are removed endoscopically under light, conscious sedation six months after the first balloon placement. Recently approved new products, the Obalon Navigation System and Obalon Touch Inflation Dispenser, are designed to further improve ease of use and convenience of placement.

Privacy and Security Laws

Medical device companies may be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the United States, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and all regulations promulgated thereunder, collectively HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Although we are not a covered entity, we may provide certain services that require the use or disclosure of PHI on behalf of physicians who are covered entities, and we therefore may be considered to be business associates under HIPAA. HIPAA imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA mandates the reporting of certain

breaches of health information to the U.S. Department of Health and Human Services, or HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations.

In addition, certain state, and non-U.S. laws, such as the European Union General Data Protection Regulation, or GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Further, "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, are also subject to certain HIPAA privacy and security standards. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation.

For example, California enacted legislation, the California Consumer Privacy Act or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate, it may regulate or impact our expected processing of personal information depending on the context. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Anti-Kickback Statutes

The federal Anti-Kickback Statute prohibits persons from (among other things) knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce the referral of an individual, or the recommending, furnishing, or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid.

Courts have interpreted the Anti-Kickback Statute quite broadly, holding that the statute will be violated if even one purpose of a payment — though not its sole or primary purpose — is to induce an act prohibited by the statute with a willful intent to act improperly. The statute prohibits many arrangements and practices

that are otherwise lawful in businesses outside of the healthcare industry. Prosecutors may infer intent from the surrounding circumstances and, because courts have interpreted the statute to be violated if even one purpose of a payment is to induce the purchase of items or services paid for by federal healthcare programs, prosecutors have broad discretion in choosing arrangements to prosecute under the statute. There are statutory exceptions and regulatory "safe harbors" available to protect certain appropriately structured arrangements that otherwise would implicate the Anti-Kickback Statute. Those who structure their business arrangements to satisfy all of the criteria of a safe harbor are protected from liability under the statute.

Penalties for violation of the Anti-Kickback Statute are severe and may include, in addition to the fines and jail time described above, penalties imposed under the Civil Monetary Penalties Law, or the CMP Law, including exclusion from participation in Federal healthcare programs, civil monetary penalties for each improper act, and damages of up to three times the amount of remuneration at issue (regardless of whether some of the remuneration was for a lawful purpose). Because we do not anticipate that the Obalon Balloon System will be reimbursed by any federal healthcare program, we do not believe that we will be subject to the federal Anti-Kickback Statute.

Many states have adopted laws similar to the Anti-Kickback Statute, however, and some of these state prohibitions apply to arrangements involving healthcare items or services reimbursed by any source, and not only by Medicare, Medicaid or another federal healthcare program. These state laws do not always have the same exceptions or safe harbors of the federal Anti-Kickback Statute. The business may be subject to some of these laws.

Government officials have focused recent enforcement efforts on the marketing of healthcare services and products, among other activities, and have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

False Claims Laws

The federal False Claims Act imposes liability on any individual or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* or "whistleblower" provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the False Claims Act and to share in any monetary recovery. In recent years, the number of lawsuits brought against healthcare industry participants by private individuals has increased dramatically.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate instance of false claim. As part of any settlement, the government may ask the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and the provision of inaccurate reimbursement coding advice, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, companies have been sued under the False Claims Act in connection with the off-label promotion of products.

Various states have also enacted false claims laws that are analogous to the federal False Claims Act. Many of these state laws apply to claims submitted to any third-party payor and are not limited to claims submitted to a federal healthcare program.

Transparency Laws

The federal Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Patient Protection and Affordable Care Act, or the PPACA, generally requires certain manufacturers of a drug, device, biologic or other medical supply that is covered by Medicare, Medicaid or the Children's Health Insurance Program and applicable group purchasing organizations to report on an annual basis: (i) certain payments and other transfers of value given to physicians (defined to include doctors, dentists, optometrists,

podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals and (ii) any ownership or investment interest that physicians, or their immediate family members, have in their company. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Under the statute, the federal government makes reported information available to the public. Failure to comply with the reporting requirements can result in significant civil monetary penalties, with additional penalties for the knowing failure to report. Additionally, there are criminal penalties if an entity intentionally makes false statements in the reports.

There has been a recent trend of separate state regulation of payments and transfers of value by manufacturers of medical devices to healthcare professionals and entities, however, and some state transparency laws apply more broadly than does the federal Sunshine Act. Our business may be subject to some of these state laws.

State Corporate Practice of Medicine, Fee-Splitting Prohibitions, and Licensure Requirements

Other regulatory oversight includes, but is not limited to, the corporate practice of medicine, fee-splitting prohibitions, and licensure and scope of practice limitations for physicians and other healthcare professionals. Some states have enacted laws and regulations limiting the extent to which physicians and certain other healthcare professionals may be employed by non-physicians or general business corporations, and the scope and provisions of corporate practice of medicines laws and regulations vary by state. These laws are intended to prevent interference in the medical decision-making process by anyone who is not a licensed physician. Violations may result in civil or criminal penalties. In addition, various state laws also generally prohibit the sharing or splitting professional fees with lay entities or persons. The specific restrictions with respect to enforcement of the corporate practice of medicine and fee-splitting laws varies from state to state. Violations of these laws could require us to restructure our operations and arrangements and may result in penalties or other adverse action.

Moreover, each state defines the scope of practice of physicians and other healthcare professionals through legislation and through their respective licensing boards, and we will need to comply with laws related to the physician supervision of services and scope of practice requirements. Activities that qualify as professional misconduct under state law may subject our personnel to sanctions or may even result in loss of their license and could, possibly, subject us to sanctions as well. Some state boards of medicine impose reciprocal discipline, that is, if a physician is disciplined for having committed professional misconduct in one state where he or she is licensed, another state where he or she is also licensed may impose the same discipline even though the conduct occurred in another state.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

International Laws

In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

U.S. Healthcare Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products. By way of example, ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the medical device industry.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge and/or patients' willingness to pay for our products. While in general it is too early to predict what effect, if any, ACA and its implementation, or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Employees

As of December 31, 2024, we had 19 employees, of which 18 were full-time and 1 was part-time. All of these employees are located in the U.S.

From time to time we also employ independent contractors, consultants and temporary employees to support our operations. None of our employees are subject to collective bargaining agreements. We have never experienced a work stoppage and believe that our relations with our employees are good.

Our Corporate Information

We were incorporated under the laws of Delaware on January 2, 2008. On June 15, 2021, we completed a merger with ReShape Lifesciences Inc. Pursuant to the Merger Agreement, a wholly owned subsidiary of Obalon with and into ReShape, with ReShape surviving the merger as a wholly owned subsidiary of Obalon. As a result of the merger, Obalon, the parent company, was renamed "ReShape Lifesciences Inc." and ReShape was renamed ReShape Weightloss Inc. ReShape Lifesciences shares of common stock trade on the Nasdaq under the symbol RSLS.

We file reports and other information with the Securities and Exchange Commission ("SEC") including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy or information statements. Those reports and statements as well as all amendments to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (1) are available at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549, (2) may be obtained by sending an electronic message to the SEC at publicinfo@sec.gov or by sending a fax to the SEC at 1-202-777-1027, (3) are available at the SEC's internet site (http://www.sec.gov), which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC and (4) are available free of charge through our website as soon as reasonably practicable after electronic filing with, or furnishing to, the SEC.

Our principal executive offices are located at 18 Technology Dr, Suite 110, Irvine, California 92618, and our telephone number is (949) 429-6680. Our website addresses are *www.reshapelifesciences.com* and *lapband.com*. The information on, or that may be accessed through, our website is not incorporated by reference into this proxy/information statement-prospectus and should not be considered a part of this proxy/ information statement-prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

Executive Compensation

Summary Compensation Table

The following table sets forth information regarding compensation earned by our named executive officers during our fiscal years ended December 31, 2024 and 2023.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Non- equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Paul F. Hickey[(1)]	2024	323,984	—	—	—	—	323,984
President and Chief Executive Officer	2023	373,083	133,000	—	—	—	506,416
Thomas Stankovich	2024	148,698	—	—	—	—	148,698
Chief Financial Officer	2023	282,121	25,000	—	—	—	307,121

Employment Agreement with Thomas Stankovich

On October 29, 2019, we entered into an employment agreement with Mr. Stankovich, our Chief Financial Officer. The agreement has an initial term of one year and automatically renews for successive one year terms unless either party delivers written notice 90 days prior to the expiration of the current term or unless it is earlier terminated. Pursuant to the agreement, Mr. Stankovich is entitled to a base salary of $300,000, or a higher annual rate if approved by the Board of Directors, and to cash and equity awards pursuant to our incentive compensation plan, contingent on Mr. Stankovich meeting certain annual objectives determined by the Compensation Committee. The agreement establishes that Mr. Stankovich is eligible for an annual incentive compensation of up to 30% of his base salary for that year. Mr. Stankovich's employment agreement also provides for the receipt of certain benefits upon the occurrence of particular termination events or a change in control. This employment agreement was amended effective December 1, 2023, whereas Mr. Stankovich and the Company mutually agreed to reduce his role to a fractional CFO, working part time on standard activities and addition for special projects as needed for an hourly rate of $125.

Employment Offer Letter and Employment Agreement with Paul Hickey

On July 25, 2022, we entered into an employment offer letter with Mr. Hickey, our President and Chief Executive Officer, pursuant to which Mr. Hickey will receive an annual base salary of $400,000 and a potential annual bonus of up to 50% of his annual base salary, which bonus for the 2022 calendar year will be prorated based on the portion of the year he is actually employed. Additionally, the offer letter provided that Mr. Hickey would be granted a stock option under the Company's equity incentive plan to purchase a number of shares of the Company's common stock equal to 4% of the Company's outstanding common stock, on a fully-diluted basis, as of the date of the offer letter. The options will have a 10-year term and a per share exercise price equal to the closing market price of the Company's common stock on the grant date. The options will vest with respect to 25% of the shares of common stock purchasable thereunder on the one-year anniversary of the grant date and monthly thereafter for 36 months, conditioned upon Mr. Hickey's continued employment with the Company from the grant date until the respective vesting date. As soon as reasonably practicable following the first offering of common stock or securities convertible into common stock for purposes of financing the Company after Mr. Hickey's start date, Mr. Hickey will be granted an additional stock option or other equity award in an amount that maintains his fully diluted ownership percentage at 4%. The offer letter contains severance provisions which provide that in the event Mr. Hickey's employment is terminated by the Company without cause or Mr. Hickey resigns for good reason, he will be entitled to receive a severance payment equal to 12 months base salary payable as salary continuation payments. To be eligible to receive these payments, Mr. Hickey will be required to execute and not revoke a

release of claims. On November 1, 2022, we entered into an employment agreement with Mr. Hickey that memorialized the terms of his employment offer letter.

Management Incentive Plan

Our Management Incentive Plan is designed to provide executive officers with annual incentive compensation based on the achievement of certain pre-established performance objectives. By utilizing a combination of objective and subjective performance factors critical to our success, this program incentivizes our executive officers to achieve results that benefit them and the Company.

At the beginning of each year, the Compensation Committee approves, subject to review by the Board of Directors, new corporate objectives for the Management Incentive Plan. The objectives are established and measured on an annual basis to better align personal objectives with the direction and objectives of the Company. When these objectives are established and approved, each objective, and, if applicable, the subparts to each objective, is weighted and assigned a percentage value relative to the corporate objectives taken as a whole. At that time, the Compensation Committee also establishes the maximum bonus amount for each of our executive officers, based on a set percentage of each executive officer's base salary, that the corporate objectives are worth. The Compensation Committee may modify or re-weight the objectives during the course of the fiscal year, if necessary, to reflect changes in our business plan.

Long-Term Incentives

Our 2022 Equity Incentive Plan, allows us the opportunity to grant stock options, restricted stock and other equity-based awards. In general, we view equity awards as incentives for future performance and not as compensation for past accomplishments. We also believe that equity awards reward continued employment by an executive officer, with an associated benefit to us of employee continuity and retention. The exercise price of stock options awarded by the Compensation Committee has been and will continue to be the closing sales price of our common stock on the date of grant.

The Compensation Committee and the Board of Directors do not grant equity awards according to a prescribed formula or target, although they review equity data from comparable companies to inform their decisions. In determining the number of equity awards granted to executive officers, individual responsibilities and experience, as well as contributions and achievements are considered, and, in appropriate circumstances, the Compensation Committee considers the recommendations of the Chief Executive Officer. The objectives utilized to assess individual contributions and achievements vary depending on the individual executive, but relate generally to strategic factors such as clinical and regulatory progress, commercialization, research and development, continued establishment of intellectual property and implementation of appropriate financing strategies. While the Chief Executive Officer may provide recommendations to the Compensation Committee regarding the number of equity awards granted to other executive officers from time to time, he does not make a recommendation as to his equity awards.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the outstanding equity award holdings held by our named executive officers at December 31, 2024.

	Stock Awards	
Name	Number of shares or units of stock that have not vested (#)[1]	Market value of shares or units of stock that have not vested ($)[2]
Paul Hickey	—	—
Thomas Stankovich	—	—

Director Compensation

Compensation for our directors is designed to result in compensation that is competitive with that provided by comparably-sized, publicly-traded, medical device companies. For 2024 (i) each non-employee

director received an annual retainer of $35,000 for serving on the Board, (ii) each non-employee director who served on the Audit Committee, the Compensation Committee or the Nominating and Governance Committee, other than the chairperson of each of the committees, received an additional annual retainer of $8,000, $5,000 and $4,500, respectively, (iii) each of the chairpersons of the Audit Committee, the Compensation Committee and the Nominating and Governance Committee received an additional annual retainer of $17,500, $10,000 and $9,000, respectively, and (iv) our Lead Director received a $15,000 annual retainer in that role.

We reimburse all of our non-employee directors for reasonable travel and other expenses incurred in attending Board and committee meetings. Directors who also serve as employees of the Company receive no additional compensation for serving as a director. Mr. Hickey is the only director who is also an employee of the Company.

In July 2022, the Board appointed Dan Gladney, who was previously the Chair of the Board of Directors, as Executive Chair. In his role as Executive Chair, Mr. Gladney will take a more active role supporting Mr. Hickey and the Company on strategic matters. Mr. Gladney's annual cash compensation for his service as the Executive Chair will be $90,000, which will replace his compensation as Chair of the Board, and is in addition to the $35,000 annual retainer paid to all Board members. Therefore Mr. Gladney's total annual cash compensation for his service on the Board and as Executive Chair will be $125,000, excluding any amounts paid for his current service on the Nominating and Governance Committee or any other committee of the Board to which he may be appointed.

The following table shows the compensation of the non-employee members of our Board during fiscal year 2024:

Director Compensation in 2024

Name[1]	Fees Earned or Paid in Cash ($)
Dan Gladney	$121,078
Gary Blackford	72,750
Lori McDougal	37,782
Arda Minocherhomjee	44,719

(1) Paul Hickey, our current President and Chief Executive Officer, is not included in this table because he received no compensation for his service as a director. The compensation that Mr. Hickey and Mr. Bandy received as an employee of the Company is shown in the "*Summary Compensation Table*."

(2) The amounts in this column include the annual Board of Director and committee retainer amounts for 2024 described above under the heading "*Director Compensation*."

MANAGEMENT

Our Board of Directors currently has five members: Gary Blackford, Dan W. Gladney, Paul Hickey, Lori McDougal and Arda Minocherhomjee, divided into three classes with staggered three-year terms. The following information has been provided with respect to the members of ReShape Lifesciences' Board of Directors.

CLASS I DIRECTORS — Continuing in office until the 2026 Annual Meeting

Dan Gladney, age 72, has served as one of our directors since November 2015, as Chairman of our Board of Directors since October 2016 and as Executive Chair since July 2022. Mr. Gladney served as our President and Chief Executive Officer from November 2015 until March 2019. Prior to joining us, Mr. Gladney served as Chairman and Chief Executive Officer of Lanx, Inc., a medical device company focused on developing and commercializing innovative devices for spinal surgery. Prior to his time at Lanx, Inc., Mr. Gladney was a Healthcare Operating Partner at Norwest Equity Partners (NEP) from 2008 until 2010, where he was responsible for strategic planning, business growth and corporate governance for NEP portfolio companies and executing new investment opportunities for the firm. Prior to joining NEP, Mr. Gladney served as President and Chief Executive Officer of several medical device companies including Heart Leaflet Technologies and ACIST Medical Systems, both of which were acquired by The Bracco Group. He also served as Chairman, Chief Executive Officer and President of Compex Technologies, a publicly traded orthopedic and health and wellness electro therapy company, from 2002 until 2006. Mr. Gladney currently serves on the board of directors of Aria CV, Inc. and has been a member of a number of other private and public company boards. After the sale of Lanx, he acted as a private investor and small business consultant.

Areas of Relevant Experience: Mr. Gladney's significant experience leading medical device companies, as well as his position as former President and Chief Executive Officer of ReShape Lifesciences and his experience with commercialization of medical device companies makes him well-suited to serve as a member of the Board of Directors.

Lori McDougal, age 63, has served as one of our directors since July 2015. Ms. McDougal has served in an executive capacity in the healthcare industry for more than eighteen years. She served as an Executive Vice President at Optum, Inc., a part of UnitedHealth Group, Inc., from 2013 until 2014. Prior to her time at Optum, she served as Chief Executive Officer of UnitedHealth Group's subsidiary UnitedHealth Military & Veterans Services, LLC from 2008 until 2013, and previously served as the Chief Operating Officer of UnitedHealth Military & Veterans Services from 2007 until 2008. Before joining UnitedHealth Military & Veterans Services, she served as a Vice President of UnitedHealthcare Medicare & Retirement starting in 2002. Additionally, she served as President of UnitedHealth International from 1998 until 2002 and Vice President of OptumInsight from 1996 to 1998.

Areas of Relevant Experience: Ms. McDougal's significant executive leadership experience and her experience working with private and government insurers, both domestic and foreign, make her well-suited to serve as a member of the Board of Directors.

CLASS II DIRECTORS — Continuing in office until the next Annual Meeting

Gary Blackford, age 67, has served as one of our directors since August 2016. From 2002 until February 2015, Mr. Blackford was the Chairman of the Board and Chief Executive Officer of Universal Hospital Services, Inc. (NYSE: UHS), a leading nationwide provider of medical technology outsourcing and services to the health care industry. Mr. Blackford was the Chief Executive Officer of Curative Health Services, Inc., a specialty pharmacy and health services company, from 2001 to 2002. He was also the Chief Executive Officer of ShopforSchool, Inc., an online retailer, from 1999 to 2001. Mr. Blackford has also been a director of Avanos Medical, Inc. (NYSE: AVNS) since 2014 (and Chairman since 2020), Children's Hospitals and Clinics of Minnesota since 2017 (and Chairman since 2020), and Lifespace Communities, Inc., a not-for-profit organization, since February 2022. He was a director of Wright Medical Group, N.V. (NASDAQ: WMGI) from 2008 to 2020 and PipelineRX, Inc. from 2016 to 2020.

Areas of Relevant Experience: Mr. Blackford's executive leadership and director experience in health care services, health benefits, medical devices, medical equipment and medical technology makes him well-suited to serve as a member of the Board of Directors.

Arda Minocherhomjee, age 71, has served as one of our directors since August 2018. Mr. Minocherhomjee is a Managing Partner of Chicago Growth Partners, which he founded in 2004. Previously, Dr. Minocherhomjee was a Managing Director at William Blair Capital Partners and, as head of the firm's Healthcare Research Group, covered multiple sectors, including drugs/drug delivery, medical devices and selected healthcare services. Mr. Minocherhomjee received a M.S. (Pharmacology) from the University of Toronto and a Ph.D. and a MBA from the University of British Columbia.

Areas of Relevant Experience: Mr. Minocherhomjee's significant experience in financial research and analysis, including financing activities, with a focus in the healthcare and medical device sectors, makes him well-suited to serve as a member of the Board of Directors.

CLASS III DIRECTOR — Continuing in office until the 2025 Annual Meeting

Paul Hickey, age 60, has served as our President and Chief Executive Officer and as one of our directors since August 15, 2022. Mr. Hickey was previously the President and Chief Executive Officer of Altimate Medical Holdings, Inc., which designs and manufactures rehabilitation medical equipment including its EasyStand brand, from February 2020 to August 2022. Previously, from 2018 to 2020, he served as the President and Chief Executive Officer of Vertebral Technologies, Inc., a medical device company focused on implantable spinal devices. Prior to that, from 2016 to 2017, Mr. Hickey was Senior Vice President of Marketing and Reimbursement for EnteroMedics (now ReShape Lifesciences). Earlier in his career, he consulted for a variety of commercialized medical device companies and held positions of increasing responsibility at Zimmer Biomet. For the past four years, Mr. Hickey has served on the Board of Directors at Excelen Center for Bone and Joint Research and Education. Mr. Hickey earned a Bachelor's degree from the University of Michigan and a Master's from Washington University in Saint Louis.

Areas of Relevant Experience: Mr. Hickey's significant experience leading medical device companies, including in his position as President and Chief Executive Officer of our company, makes him well-suited to serve as a member of the Board of Directors.

Executive Officers

Thomas Stankovich, age 64, has served as our Chief Financial Officer since October 2019. Mr. Stankovich has over 25 years of executive leadership experience as the CFO for multiple public and private healthcare companies. Prior to joining us, Mr. Stankovich spent the past nine years as the Global Senior Vice President and CFO of MP Biomedicals, a life sciences and molecular biology-diagnostics company. At MP Biomedicals he was responsible for financial planning and reporting, operations and strategy development along with the acquisition and integration of two international companies. Prior to MP Biomedicals, Mr. Stankovich served as CFO at Response Genetics where he successfully led the company through their initial public offering. Additionally, he served as CFO for Cobalis Corporation and Ribapharm, where he also led the company through their initial public offering, which at the time became the second largest ever IPO in the biotechnology sector. Mr. Stankovich also held CFO positions at ICN International which later changed names to Valeant Pharmaceuticals.

Director Independence

Our Board of Directors reviews at least annually the independence of each director. During these reviews, our Board of Directors considers transactions and relationships between each director (and his or her immediate family and affiliates), ReShape Lifesciences and our management to determine whether any such transactions or relationships are inconsistent with a determination that the director was independent. This review is based primarily on responses of the directors to questions in a directors' and officers' questionnaire regarding employment, business, familial, compensation and other relationships with ReShape Lifesciences and our management. Our Board of Directors has determined that no transactions or relationships existed that would disqualify any of our directors under the Nasdaq Stock Market rules or require disclosure under SEC rules, with the exception of Paul Hickey, our President and Chief Executive Officer, because of his current employment relationship with ReShape Lifesciences. Based upon that finding, the Board of Directors determined that Ms. McDougal and Messrs. Blackford, Gladney and Minocherhomjee are "independent" and the composition of our Board of Directors meets the requirements for independence

under the Nasdaq Stock Market. Each of our Audit, Compensation, and Nominating and Governance Committees is composed only of independent directors.

Director Qualifications and Selection Process

The Nominating and Governance Committee determines the required selection criteria and qualifications of director nominees based upon the needs of the Company at the time nominees are considered. Directors should possess the highest personal and professional ethics, integrity and values, and be committed to representing the long-term interests of our stockholders. In evaluating a candidate for nomination as a director of the Company, the Nominating and Governance Committee will consider criteria including business and financial expertise; experience in the medical device industry or other fields of scientific or medical endeavor; experience as a director of a public company; and general criteria such as ethical standards, independent thought, practical wisdom and mature judgment. The Nominating and Governance Committee will consider these criteria for nominees identified by the committee, by stockholders, or through some other source. The Nominating and Governance Committee does not have a formal policy with regard to the consideration of diversity in identifying director nominees. The Board evaluates each individual in the context of the Board as a whole, with the objective of assembling a group that can best perpetuate the success of our business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

These general criteria are subject to modification and the Nominating and Governance Committee will be able, in the exercise of its discretion, to deviate from these general criteria from time to time, as the committee may deem appropriate or as required by applicable laws and regulations.

The Nominating and Governance Committee makes a preliminary assessment of each proposed nominee based upon the resume and biographical information, an indication of the individual's willingness to serve and other background information. This information is evaluated against the criteria set forth above and the Company's specific needs at that time. Based upon a preliminary assessment of the candidate(s), those who appear best suited to meet the Company's needs may be invited to participate in a series of interviews, which are used as a further means of evaluating potential candidates. On the basis of information learned during this process, the Nominating and Governance Committee determines which nominee(s) to recommend to the Board of Directors to submit for election at our next annual meeting. The Nominating and Governance Committee uses the same process for evaluating all nominees, regardless of the original source of the nomination.

No candidates for director nominations were submitted to the Nominating and Governance Committee by any stockholder in connection with the annual meeting.

Board Leadership Structure

Mr. Gladney serves as our Executive Chair of the Board and Mr. Blackford serves as our Lead Director. The Board believes that having Mr. Gladney serve as the Executive Chair of the Board ensures that Mr. Hickey, our President and Chief Executive Officer, can focus on the operational and strategic priorities of the Company. While Mr. Gladney is an independent director under the Nasdaq Stock Market standards, the Board believes it is appropriate to also have an independent Lead Director given Mr. Gladney previously served as the Company's President and Chief Executive Officer and now serves as the Executive Chair, which is a role designed to support Mr. Hickey and the Company in strategic matters. As Lead Director, Mr. Blackford presides at executive sessions of the non-employee directors and serves as a liaison between the Executive Chair and the Board, to ensure the efficient and independent operation of the Board.

Each of the directors other than Mr. Hickey is independent and our Board believes that the Executive Chair, Lead Director and other independent directors provide effective oversight of management. Moreover, in addition to the feedback provided during the course of the Board meetings, the independent directors have regular executive sessions. At the executive sessions, the independent directors discuss specific feedback or issues to be discussed with the President and Chief Executive Officer, provide the Executive Chair and Lead Director with input regarding agenda items for Board and Committee meetings and coordinate with the Executive Chair and Lead Director regarding information to be provided to the independent directors in

performing their duties. Our Board believes that this approach is appropriate to ensure proper oversight of our executives and effectively complements our current management structure.

Our Board of Directors periodically evaluates whether the leadership structure of our Board continues to be optimal for the Company and our stockholders. Although we believe that separation of the Executive Chair and Chief Executive Officer roles and the inclusion of a Lead Director role is appropriate in our current circumstances, the Board has the flexibility to modify the Board leadership structure in the future if it determines that to be appropriate.

Board Meetings and Committees

The Board of Directors conducts its business through meetings of the Board and the following standing committees: Audit, Nominating and Governance, and Compensation. The standing committees regularly report on their activities and actions to the full Board. Each of the standing committees has the authority to engage outside experts, advisors and counsel to the extent it considers appropriate to assist the committee in its work. Each of the standing committees has adopted and operates under a written charter. These charters can be found on the Corporate Governance section of the Investors page on our website at www.reshapelifesciences.com. Stockholders may request a free printed copy of any of these charters by contacting our Secretary at ReShape Lifesciences Inc., 18 Technology Drive, Suite 110, Irvine, California 92618.

The following table reflects the current membership of each Board committee.

Committee Membership

Name	Audit	Nominating and Governance	Compensation
Gary Blackford	✓	Chair	Chair
Dan Gladney		✓	
Lori McDougal	✓		✓
Arda Minocherhomjee	Chair	✓	✓

Audit Committee

The Audit Committee is responsible for assisting the Board in monitoring the quality and integrity of our consolidated financial statements, our internal controls, our compliance with legal and regulatory requirements and the qualifications, performance and independence of our independent auditor. The Audit Committee has sole authority to retain and terminate the independent auditor and is directly responsible for the compensation and oversight of the work of the independent auditor. The Audit Committee reviews and discusses with management and the independent auditor the annual audited and quarterly consolidated financial statements (including the disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023), reviews the integrity of the financial reporting processes, both internal and external, reviews the qualifications, performance and independence of the independent auditor, oversees the Company's compliance with legal and regulatory requirements with respect to financial matters, and prepares the Audit Committee Report included in the proxy statement in accordance with the rules and regulations of the SEC. All of the Audit Committee members meet the existing independence and experience requirements of the Nasdaq Stock Market and the SEC. Our Board of Directors has determined that Arda Minocherhomjee, our current Audit Committee Chair, is a financial expert under the rules of the SEC. During each of the meetings, the Audit Committee met in private session with our independent auditor and alone in executive session without members of management present.

Nominating and Governance Committee

The Nominating and Governance Committee is responsible for assisting the Board by identifying individuals qualified to become Board members and the independent directors on the Nominating and Governance Committee are responsible for recommending to the Board the nominees for election as directors

at our next annual meeting of stockholders. The Nominating and Governance Committee also manages the performance review process for our current directors, recommends qualified members of the Board for membership on committees, conducts a preliminary assessment of the independence of all Board members, reviews the charters of all Board committees, reviews and evaluates succession plans for executive officers, reviews and makes recommendations to the Board regarding our corporate governance principles, oversees the Company's compliance with legal and regulatory requirements (other than those with respect to financial matters that are overseen by the Audit Committee) and processes and makes recommendations to the Board regarding any stockholder proposals. All of the Nominating and Governance Committee members meet the existing independence requirements of the Nasdaq Stock Market. During each of the meetings, the Nominating and Governance Committee held an executive session without members of management present.

Compensation Committee

The Compensation Committee is responsible for assisting the Board by overseeing the administration of our compensation programs and reviewing and approving the compensation paid to our executive officers. The Compensation Committee approves corporate goals related to the compensation of the Chief Executive Officer, evaluates the Chief Executive Officer's performance, determines the compensation of the Chief Executive Officer based on this evaluation, and recommends our non-employee director compensation to the Board. All of the Compensation Committee members meet the existing independence requirements of the Nasdaq Stock Market. During each of the meetings, the Compensation Committee held an executive session without members of management present.

The Compensation Committee reviews and approves the compensation programs and all forms of compensation for our Chief Executive Officer and for our other executive officers. The Chief Executive Officer's compensation package is set by the Compensation Committee in its sole discretion. Although our Chief Executive Officer does not make a recommendation as to his own compensation, he may respond to the Compensation Committee's proposal for his compensation, which the Compensation Committee may, but is not required to, consider. The Chief Executive Officer is also permitted to make compensation recommendations for the other executive officers, which the Compensation Committee may, but is not required to, consider. In addition, the Chief Executive Officer may participate as an observer at the Compensation Committee's meetings when the committee invites him to attend its meetings. Other than these rights granted to the Chief Executive Officer, management does not participate in the determination of the amount or form of executive compensation.

In general, the Compensation Committee tries to keep each executive officer's base salary and total compensation at the midpoint of the range of base salaries and total compensation paid to similar executive officers at comparable companies and may make recommendations to adjust an executive officer's compensation accordingly. The goal of this review is to try to maintain base salaries and total compensation packages that are market competitive, so the Company can attract and retain executive talent. However, the Compensation Committee may deviate from this benchmark as it considers other factors such as each executive officer's individual performance and responsibilities, the Company's overall strategy and performance and the pool of resources available for compensation adjustments each year. These factors, especially the Company's desire to reward individual efforts and performance, weigh much more heavily in the Compensation Committee's final recommendations with respect to compensation adjustments. Since the Company's intent with respect to stock-based compensation relates more to aligning executive officers' interests with those of the Company and encouraging their efforts for the long-term growth and success of the Company, the peer group analysis generally plays a role as a reference point in the Compensation Committee's decisions to make additional awards of stock options to the executive officers. More importantly, the Compensation Committee considers individual performance and experience, contributions and achievements, stock option grants previously awarded to each executive and the Compensation Committee's view of the appropriate levels of equity compensation for individuals with certain responsibilities, professional expertise and experience.

The Compensation Committee has the authority to use outside compensation consultants to assist it in analyzing our compensation programs and determining appropriate levels of compensation and benefits or to retain outside counsel and other advisors to assist it in the performance of its functions. The decision to retain consultants and, if so, which consultants to retain, is made solely by the Compensation Committee.

Executive Sessions of the Board

Our non-employee directors meet in executive session at each regular meeting of the Board without the Chief Executive Officer or any other member of management present.

Attendance at the Annual Meeting

Our Board of Directors encourages each of its members to attend the annual meeting of stockholders.

Code of Business Conduct and Ethics

We have adopted the ReShape Lifesciences Inc. Code of Business Conduct and Ethics, which applies to all of our employees, officers and directors. The Code of Business Conduct and Ethics includes particular provisions applicable to our senior financial management, which includes our Chief Executive Officer, Chief Financial Officer, Controller and other employees performing similar functions. A copy of our Code of Business Conduct and Ethics is available on the Corporate Governance section of the Investors page on our website at www.reshapelifesciences.com. We intend to post on our website any amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics that applies to any director or officer, including our principal executive officer, principal financial officer, principal accounting officer, controller and other persons performing similar functions, promptly following the date of such amendment or waiver.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our Board of Directors or Compensation Committee. None of the current members of the Compensation Committee of our Board has ever been one of our employees.

Board's Role in Risk Oversight

Our management has responsibility for managing day-to-day risk and for bringing the most material risks facing the Company to the Board's attention. The Board takes an active role in risk oversight related to the Company both as a full Board and through its committees. To facilitate the Board's risk oversight responsibility, management provides the Board with information about its identification, assessment and management of critical risks and its risk mitigation strategies. This information is communicated to our Board and committees at regular and special meetings, through reports, presentations and discussions with key management personnel and representatives of outside advisors, such as our independent auditors, as appropriate. These matters are further discussed by the Board and committees in executive sessions without the presence of management. The primary areas of risk oversight that our Board and committees are responsible for are summarized below:

Board/Committee	Primary Areas of Risk Oversight
Full Board	Strategic, financial and execution risks and exposures associated with the annual capital plan and strategic plans (including capital allocation); litigation and regulatory exposures; other current matters that may present material risk to our operations, plans, prospects or reputation; and senior management succession planning.
Audit Committee	Risks and exposures associated with financial matters, particularly financial reporting, tax, accounting, disclosure, internal control over financial reporting, financial policies, investment guidelines and credit and liquidity matters, and compliance with legal and regulatory requirements with respect to financial matters.

Board/Committee	Primary Areas of Risk Oversight
Compensation Committee	Risks and exposures associated with leadership assessment, management succession planning and executive compensation programs and arrangements, including incentive plans.
Nominating and Governance Committee	Risks and exposures associated with corporate governance, legal and regulatory compliance (other than with respect to financial matters that are overseen by the Audit Committee) and director succession planning.

Review of Related Person Transactions

In accordance with its written charter, our Audit Committee is responsible for reviewing all related party transactions as they are presented, and the approval of the Audit Committee is required for all such transactions. The term "related party transactions" refers to transactions required to be disclosed in our filings with the SEC pursuant to Item 404 of Regulation S-K. As a smaller reporting company, we are also required to review and approve any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person has a direct or indirect material interest. In considering related party transactions, our Audit Committee is guided by its fiduciary duty to our stockholders. Our Audit Committee does not have any written or oral policies or procedures regarding the review, approval and ratification of transactions with related parties. Additionally, each of our directors and executive officers are required to annually complete a directors' and officers' questionnaire that elicits information about related party transactions. Our Nominating and Governance Committee and Board of Directors annually review all transactions and relationships disclosed in the director and officer questionnaires, and the Board makes a formal determination regarding each director's independence.

Anti-Hedging and Anti-Pledging Policies

We consider it improper and inappropriate for any director, officer or other employee of our company to engage in short-term or speculative transactions in our securities. Therefore, our insider trading policy provides that our directors, officers and other employees may not engage in specified hedging and pledging transactions. Specifically, our insider trading policy (i) requires any of our directors, officers or employees to pre-clear any proposed hedging transaction, including zero-cost collars and forward sales contracts and other similar transactions that allow such person to continue to own the covered security without the full risks and rewards of ownership, with our Board of Directors and (ii) prohibits our directors, officers and employees from holding our securities in a margin account or pledging our securities as collateral for a loan.

Indemnification Agreements

It is our standard practice to enter into an indemnification agreement with each executive officer and member of our Board of Directors. Each indemnification agreement provides that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as our director, officer, employee or agent, provided that he or she acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe that his or her conduct was unlawful. If the claim is brought by us or on our behalf, we will not be obligated to indemnify the director or executive officer if he or she is found liable to us; unless the court determines that, despite the adjudication of liability, in view of all the circumstances of the case the director is fairly and reasonably entitled to indemnity. In the event that we do not assume the defense of a claim against our director or executive officer, we are required to advance his or her expenses in connection with his or her defense, provided that he or she undertakes to repay all amounts advanced if it is ultimately determined that he or she is not entitled to be indemnified by us.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows the beneficial ownership of ReShape's common stock by each person or group who beneficially owned 5% or more of ReShape's common stock, each of ReShape's directors, each of the executive officers of ReShape named in the Summary Compensation Table in this proxy/information statement-prospectus and ReShape's directors and executive officers as a group, as of January 9, 2025.

Percentage ownership calculations for beneficial ownership are based on 729,980 shares outstanding as of January 9, 2025. However, for purposes of computing the percentage of outstanding shares of common stock held by each person or group of persons named above, any shares which that person or persons has or have the right to acquire within 60 days following January 9, 2025 is deemed to be outstanding for that person's calculation, but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. The information regarding the beneficial owners of more than 5% of ReShape's common stock is based upon information supplied to ReShape by its directors, officers and principal stockholders or on Schedules 13D or 13G filed with the Securities and Exchange Commission. Unless otherwise noted, the directors and executive officers listed in the table have sole voting and investment power with respect to the shares of common stock owned by them and their address is c/o ReShape Lifesciences Inc., 18 Technology Dr., Suite 110, Irvine, California 92618.

Title of Class	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Common Stock	**Directors and Executive Officers**		
	Paul Hickey	—	*
	Thomas Stankovich	393	*
	Dan Gladney	15	*
	Gary Blackford	—	*
	Arda Minocherhomjee	—	*
	Lori McDougal	—	*
	All directors and executive officers as a group (6 persons)	408	*
Common Stock	**5% Stockholders**		
	Ascent Partners Fund LLC[(1)] 256 W. 38th Street, 15th Floor New York, New York 10018	78,307	10.7%
	Yair Schneid[(2)] 1 Wood Lane Suffern, New York 10901	37,407	5.1%

* The percentage of shares of common stock beneficially owned does not exceed one percent of the outstanding shares of common stock.

(1) Based in part on information contained in a Schedule 13D filed with the SEC on January 7, 2025 by (i) Dominion Capital LLC, a Connecticut limited liability company ("Dominion"), (ii) Dominion Capital GP LLC, a Delaware limited liability company ("Dominion GP"), (iii) Dominion Capital Holdings LLC, a Delaware limited liability company ("Dominion Holdings"), (iv) Ascent Partners Fund LLC, a Delaware limited liability company ("Ascent"), (v) Mikhail Gurevich, (vi) Gennadiy Gurevich, and (vii) Alon Brenner. The principal business of Ascent is to make and hold investments. Ascent is a subsidiary of Dominion. Ascent has the power to dispose of and the power to vote the shares of ReShape Common Stock beneficially owned by it, which power may be exercised by its parent, Dominion. Dominion has the power to dispose of and the power to vote the shares of ReShape Common Stock beneficially owned by it and Ascent, which power may be exercised by Dominion's manager, Dominion GP. Dominion Holdings is the manager of Dominion GP. Each of the managing members of Dominion Holdings, Mikhail Gurevich and Gennadiy Gurevich, has shared power to vote and/or dispose of the shares of ReShape Common Stock beneficially owned by Ascent, Dominion, Dominion

GP and Dominion Holdings. As managing member of Ascent, Alon Brenner has the power to dispose of the shares of ReShape Common Stock beneficially owned by Ascent. Neither Mikhail Gurevich, Gennadiy Gurevich nor Alon Brenner directly owns such shares of ReShape Common Stock. By reason of the provisions of Rule 13d-3 of the Exchange Act, each of Mikhail Gurevich, Gennadiy Gurevich and Alon Brenner may be deemed to beneficially own the shares of ReShape Common Stock which are beneficially owned by each of Ascent, Dominion, Dominion GP and Dominion Holdings. Dominion Holdings may be deemed to beneficially own the shares of ReShape Common Stock which are beneficially owned by each of Ascent, Dominion and Dominion GP, and Dominion GP may be deemed to beneficially own the shares of ReShape Common Stock which are beneficially owned by Ascent and Dominion, and Dominion may be deemed to beneficially own the shares of ReShape Common Stock which are beneficially owned by Ascent.

(2) Based in part on information contained in a Schedule 13G/A filed with the SEC on September 26, 2024.

DESCRIPTION OF EQUITY FINANCING TRANSACTION

General

On December 19, 2024, we entered into a common stock purchase agreement (the "Equity Purchase Agreement") with Ascent Partners Fund LLC ("Ascent") pursuant to which Ascent has agreed to purchase from the Company, at the Company's direction from time to time, in its sole discretion, from and after the effectiveness of the definitive documentation (the "Effective Date"), and until the earlier of (i) the 36-month anniversary of the Effective Date or (ii) the termination of the Equity Purchase Agreement in accordance with the terms thereof (the "Commitment Period"), shares of our common stock having a total maximum aggregate purchase price of $5,000,000 (the "Purchase Shares"), upon the terms and subject to the conditions and limitations set forth therein.

As consideration for its commitment to purchase our common stock under the Equity Purchase Agreement, on December 19, 2024, we issued 17,300 shares of our common stock to Ascent, including 21,015 shares issuable upon exercise of a pre-funded warrant. Ascent has agreed to hold these commitment shares, subject to a 9.99% beneficial ownership limitation, through the record date for the meeting of our stockholders to be held to approve, among other things, the Merger with Vyome and Asset Sale to Biorad and will vote such shares in favor of all management proposals at such meeting.

Purchase of Shares of Common Stock Under the Equity Purchase Agreement

During the Commitment Period, we may, from time to time and at our sole discretion, direct Ascent to purchase such number of shares of our common stock (the "Issuance Notice") that does not exceed (a) if the Issuance Notice is received prior to 9:00 a.m. Eastern Standard Time, the lesser of: (i) an amount equal to 12.5% of the aggregate daily traded volume of our common stock on Nasdaq for the ten (10) trading days immediately preceding the date of such closing and (ii) a purchase price of $500,000 and (b) otherwise, the lesser of: (i) 7.5% of the aggregate daily traded volume of our common stock on Nasdaq for the ten (10) trading days immediately preceding the date of such closing and (ii) a purchase price of $250,000. The price paid for each share of our common stock at each closing shall be 93% of the volume-weighted average price of our common stock ("VWAP") on the trading day prior to such closing; provided, that if 93% of the lowest VWAP in the four trading days following such closing is lower than such share price, then, as a true-up, we shall issue additional shares of our common stock to Ascent so as to ensure that the total number of shares received by Ascent is equal to the number it would have received for the aggregate purchase price paid at such closing if the shares of our common stock had bene valued at such lower number.

We will control the timing and amount of any sales of our common stock to Ascent, and Ascent has no right to require us to sell any shares to it under the Equity Purchase Agreement. Actual sales of shares of common stock to Ascent under the Equity Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including (among others) market conditions, the trading price of our common stock and determinations by us as to available and appropriate sources of funding for ReShape and its operations. Ascent may not assign its rights and obligations under the Equity Purchase Agreement.

The Equity Purchase Agreement prohibits us from directing Ascent to purchase any shares of our common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Ascent and its affiliates (as calculated pursuant to Section 13(d) of the Securities Exchange Act and Rule 13d-3 thereunder), would result in Ascent and its affiliates beneficially owning more than 9.99% of the then total outstanding shares of our common stock.

If we fail to issue and deliver the shares purchased pursuant to an Issuance Notice to Ascent within two trading days of the issuance of an Issuance Notice or fail to have any restrictive legends removed from any shares purchased pursuant to an Issuance Notice, we will be considered in breach of our obligations under the Equity Purchase Agreement.

The Equity Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions. Sales under the Equity Purchase Agreement may commence only after certain conditions have been satisfied, including effectiveness of a resale registration statement.

Termination of the Equity Purchase Agreement

Unless earlier terminated as provided in the Equity Purchase Agreement, the Equity Purchase Agreement will terminate automatically on the earliest to occur of: (i) the first day of the month next following the 36 month anniversary of the Effective Date, or (ii) the date on which Ascent shall have purchased shares of our common stock under the Equity Purchase Agreement for an aggregate gross purchase price equal to $5,000,000.

We have the right to terminate the Equity Purchase Agreement at any time for any reason or for no reason, without any liability whatsoever, upon five trading days' prior written notice to Ascent, provided that (i) there are no outstanding Issuance Notices, the common stock under which have yet to be issued, and (ii) we have paid all amounts owed to Ascent pursuant to the Equity Purchase Agreement.

ReShape and Ascent also have the option to terminate the Equity Purchase Agreement by mutual written consent, which shall be effective as of the date of such mutual written consent unless otherwise provided in such written consent.

No Short-Selling or Hedging by Ascent

Ascent has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Equity Purchase Agreement.

Registration Rights Granted to Ascent

As provided under the Equity Purchase Agreement, we agreed to file a registration statement with the SEC covering the resale of the shares of our common stock issued to Ascent pursuant to the Equity Purchase Agreement. We shall also use commercially reasonable efforts to continuously maintain the effectiveness of such registration statement until all of the Purchase Shares have been sold or may be sold without restriction pursuant to Rule 144 of the Securities Act.

DESCRIPTION OF CONVERTIBLE NOTE TRANSACTION

In a private transaction, on October 16, 2024, we entered into a securities purchase agreement (the "SPA") with Ascent. Pursuant to the SPA, we agreed to issue to Ascent a senior secured convertible note in the aggregate original principal amount of $833,333.34 (the "Note"), and also issued to Ascent 7,983 shares of common stock as "commitment shares" to Ascent.

We are the issuer of the Note, and our subsidiaries are guaranteeing the obligations under the Note pursuant to a Guaranty, dated October 16, 2024. The Note is fully secured by collateral of ReShape and our subsidiaries. The security interest in favor of Ascent, as collateral agent, covers substantially all assets of ReShape including, without limitation, the intellectual property, trademark, and patent rights of ReShape. The parties entered into a Security Agreement and certain intellectual property security agreements granting such security interest in favor of Ascent.

Note. In connection with the SPA, we issued to Ascent the Note on October 16, 2024, which bears an interest rate of 10% per annum and was initially due and payable on the earlier of (i) January 16, 2025 and (ii) the date of consummation or termination of our previously announced merger with Vyome Therapeutics, Inc. The initial conversion price of the Note is $5.22 per share of common stock. The Note may not be converted by Ascent into shares of common stock if such conversion would result in Ascent and its affiliates owning in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of all shares issuable upon conversion of the Note. The Note provides for certain events of default that are typical for a transaction of this type, including, among other things, any breach of the representations or warranties made by ReShape or its subsidiaries. In connection with any event of default that results in the acceleration of payment of the Note and while it is continuing, the interest rate on the Note shall accrue at an interest rate equal to the lesser of 24% per annum or the maximum rate permitted under applicable law.

On January 14, 2025, we entered into an amendment to the Note with Ascent to (a) extend the maturity date to the earlier of the closing of the Company's merger with Vyome or 90 days after the date of the amendment, (b) provide that Ascent would not be obligated to convert any part of the Note at the closing of the merger, (c) reduce the mandatory prepayment provision for funds raised by the Company in subsequent financings from 66% to 50%, and (d) require a $45,000 cash extension fee to be paid by the Company at the maturity of the Note.

Registration Rights Agreement. In connection with the SPA, we entered into a Registration Rights Agreement with Ascent, dated October 16, 2024 (the "RRA"). The RRA provides that we will file a registration statement to register the shares of common stock underlying the Note and the commitment shares within 30 days after the date of the SPA and will use its best efforts to cause the registration statement to be declared effective within 30 days after the filing date.

Lock-Up Agreement. In connection with the SPA, the directors and officers of ReShape each entered into a lock-up agreement (the "Lock-Up Agreement"), pursuant to which each agreed to, from the date of the Lock-Up Agreement until the Note is no longer outstanding, subject to certain customary exceptions, not offer, sell, contract to sell, hypothecate, pledge or otherwise dispose of any shares of common stock of ReShape or securities convertible, exchangeable or exercisable into, shares of common stock of ReShape beneficially owned, held or acquired by the person signing the Lock-Up Agreement.

Leak-Out Agreement. In connection with the SPA, we entered into a Leak-Out Agreement with Ascent, dated October 16, 2024, pursuant to which Ascent agreed that on any trading day while the Note, or shares of common stock issued to Ascent upon conversion of the Note, remains outstanding, Ascent will not, and will cause each of its trading affiliates not to, sell, dispose or otherwise transfer, in the aggregate, more than 10% of the composite daily trading volume of the common stock as reported by Bloomberg, LP.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights of our common and preferred stock and some of the provisions of our charter and bylaws and of the Delaware General Corporation Law, or DGCL. Our authorized capital stock consists of 300,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.001 par value per share.

As of January 15, 2025, there were 729,980 shares of our common stock outstanding, held by approximately 40 stockholders of record, and 95,388 shares of our series C convertible preferred stock outstanding.

Common Stock

Voting rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We do not provide for cumulative voting for the election of directors in our charter. Accordingly, holders of a majority of the shares of our common stock are able to elect all of our directors. Our charter establishes a classified board of directors, to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our charter and bylaws provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our charter.

Dividend rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our Board, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

No preemptive or similar rights

Our common stock is not entitled to preemptive or subscription rights, and is not subject to conversion, redemption or sinking fund provisions. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Right to receive liquidation distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

Pursuant to our charter, our Board is authorized, subject to limitations prescribed by Delaware law, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our Board is able to increase or decrease the number

of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our Board may be able to authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

Series C Convertible Preferred Stock

The material terms and provisions of the shares of series C convertible preferred stock ("Series C Preferred Stock") are summarized below. This summary of some provisions of the Series C Preferred Stock is not complete. For the complete terms of the Series C Preferred Stock, you should refer to the Certificate of Designation (the "Series C Certificate of Designation") filed as an exhibit to this prospectus and incorporated herein by reference.

Conversion. There are currently 95,388 shares of our series C convertible preferred stock outstanding. Each outstanding share of Series C Preferred Stock is convertible, at the option of the holders, into 0.0000078 shares of common stock, rounded up to the nearest whole share, subject to adjustments for stock splits, stock dividends, distributions, subdivisions and combinations. Therefore, as of the date of this prospectus, each of the 10 holders of Series C Preferred Stock is entitled to convert all of their shares of Series C Preferred Stock into an aggregate of one share of common stock per holder.

Dividends. The Series C Preferred Stock is entitled to receive dividends (on an as-if-converted-to-common stock basis) actually paid on shares of common stock when, as and if such dividends are paid on shares of common stock. No other dividends will be paid on shares of Series C Preferred Stock.

Voting Rights. In general, the Series C Preferred Stock does not have voting rights. However, as long as any shares of Series C Preferred Stock remain outstanding, the Series C Certificate of Designation provides that we cannot, without the affirmative vote of holders of a majority of the then-outstanding shares of Series C Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series C Preferred Stock (including by the designation, authorization, or issuance of any shares of preferred stock that purports to have equal rights with, or be senior in rights or preferences to, the Series C Preferred Stock), (b) alter or amend the Series C Certificate of Designation, (c) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series C Preferred Stock, (d) increase the number of authorized shares of Series C Preferred Stock, (e) except for stock dividends or distributions for which adjustments are to be made pursuant to the Series C Certificate of Designation, pay dividends on any shares of capital stock of the Company, or (f) enter into any agreement with respect to any of the foregoing. Holders of Series C Preferred Stock are entitled to vote for the election of directors of the Company, voting on an as-converted to common stock basis and voting together as a single class with the holders of shares of common stock.

Liquidation. In the event of a liquidation, the holders of shares of Series C Preferred Stock are entitled to be paid, after and subject to the payment in full of all amounts required to be distributed to the holders of any other shares of the Company outstanding as of the date of our acquisition of ReShape Medical ranking on liquidation prior and in preference to the Series C Preferred Stock, but before any payments to be made to the holders of common stock or any other series of preferred stock, an amount per share equal to the greater of (i) $274.8774, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series C Preferred Stock been converted to common stock immediately prior to such liquidation. In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series C Preferred Stock will be entitled to receive upon conversion of the Series C Preferred Stock the same kind and amount of securities, cash or property which the holders would have received had they converted the Series C Preferred

Stock immediately prior to such fundamental transaction. Any successor to us or surviving entity must assume the obligations under the Series C Certificate of Designation with respect to the Series C Preferred Stock.

Stock Options

As of January 15, 2025, we had outstanding options to purchase an aggregate of 144 shares of our common stock, with a weighted-average exercise price of approximately $34,101 per share.

Restricted Stock Units

As of January 15, 2025, we had 8 restricted stock units outstanding.

Warrants

As of January 15, 2025, we had outstanding warrants to purchase an aggregate of 81,384 shares of our common stock with expiration dates ranging from 2023 to 2028.

We have agreed to file a registration statement providing for the resale by the purchaser of the warrants issued in a private placement on November 9, 2022, and to keep such registration statement effective at all times until the purchaser no longer owns any such warrants or shares of common stock issuable upon exercise thereof.

Anti-Takeover Provisions

The provisions of Delaware law, our charter and our bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware law

We are subject to the provisions of Section 203 of the DGCL, or Section 203, regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination

of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Charter and bylaw provisions

Our charter and our bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- *Board of Directors Vacancies*. Our charter and bylaws authorize only our Board to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our Board will be permitted to be set only by a resolution adopted by a majority vote of our entire Board. These provisions would prevent a stockholder from increasing the size of our Board and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our Board but promotes continuity of management.
- *Classified Board*. Our charter and bylaws provide that our Board be classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time-consuming for stockholders to replace a majority of the directors on a classified board of directors.
- *Stockholder Action; Special Meetings of Stockholders*. Our charter provides that our stockholders may not take action by written consent but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws and charter provide that special meetings of our stockholders may be called only by a majority of our Board, the chairman of our Board, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.
- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempt to obtain control of our company.
- *No Cumulative Voting*. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our charter does not provide for cumulative voting.
- *Directors Removed Only for Cause*. Our charter provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.
- *Amendment of Charter Provisions*. Any amendment of the above expected provisions in our charter would require approval by holders of at least two-thirds of our outstanding common stock, unless such amendment is approved by at least two-thirds of our directors, in which case the amendment may be approved by the holders of a majority of our outstanding common stock.
- *Issuance of Undesignated Preferred Stock*. Our Board has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board. The existence of

authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

- *Choice of Forum*. Our charter provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our charter or our bylaws; any action to interpret, apply, enforce or determine the validity of our charter or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent's address is 48 Wall Street, 22nd Floor, New York, NY 10005, and its telephone number is (800) 937-5449.

DESCRIPTION OF SECURITIES WE ARE OFFERING

Common Stock

The material terms and provisions of our Common Stock are described under the caption "Description of Capital Stock."

Warrants

The following summary of certain terms and conditions of the Warrants is not complete and is subject to, and qualified in its entirety by, the provisions of Warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Warrant for a complete description of the terms and conditions of the Warrants.

Warrant Stockholder Approval

Under Nasdaq listing rules, the Warrants are not exercisable without stockholder approval. We have agreed to hold a stockholders' meeting in order to seek such stockholder approvals as may be required by the applicable rules and regulations of the Nasdaq Capital Market (or any successor entity) from our stockholders in order to permit the exercise of the Warrants. We have agreed to file a preliminary proxy statement to seek Warrant Stockholder Approval within five days of the closing date of this offering and to hold the meeting no later than 45 days after the closing date of this offering. We cannot assure you that we will be able to hold the meeting in this timeframe or obtain this requisite approval. In the event that we are unable to obtain the Warrant Stockholder Approval, the Warrants will not be exercisable and therefore have no value.

Duration and Exercise Price

Each Warrant offered hereby will have an initial exercise price per share equal to no less than 100% and no more than 300% of the Unit offering price. The Warrants will be immediately exercisable one trading day after notice is given to the warrant holders that Warrant Stockholder Approval has been obtained and will expire on the later of (i) twelve (12) days after date of Warrant Stockholder Approval and (ii) the earlier of (x) the closing date of the transaction contemplated by the Merger and (y) sixty (60) days after the date of Warrant Stockholder Approval. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our shares of Common Stock and the exercise price. The Warrants contain a one-time reset of the exercise price (subject to a floor of $1.25 per share) to a price equal to the lowest VWAP for our Common Stock during the period beginning four trading days immediately prior to the effective date of the Warrant Stockholder Approval and ending four trading days after the effective date of Warrant Stockholder Approval (the "Reset Date"). Any reset of the exercise price of the Warrants will occur on the Reset Date. If a reset of the exercise price of the Warrants occurs, the number of shares of our Common Stock underlying the Warrants will also be increased on the Reset Date so that the reset exercise price multiplied by increased number of shares equal the aggregate proceeds that would have resulted from the full exercise of the Warrants immediately prior to the Rest Date. We have agreed not to consummate the Merger until at least 12 trading days after Warrant Stockholder Approval has been obtained.

Form

Warrants will be issued in certificated form as individual warrant agreements to the investors.

Exercisability

The Warrants are not exercisable without first obtaining the Warrant Stockholder Approval. Assuming the Warrant Stockholder Approval is obtained, the Warrants will be exercisable, at the option of the holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of Common Stock purchased upon such exercise (except in the case of a cashless exercise or alternative cashless exercise, as discussed below). A holder (together with its affiliates) may not

exercise any portion of the Warrants to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding shares of Common Stock immediately after exercise. However, upon notice from the holder to us, the holder may decrease or increase the holder's beneficial ownership limitation, which may not exceed 9.99% of the number of outstanding shares of Common Stock immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants, provided that any increase in the beneficial ownership limitation will not take effect until 61 days following notice to us. Purchasers in this offering may also elect, prior to the issuance of the Warrants, to have the initial exercise limitation set at 9.99% of our outstanding shares of Common Stock. No fractional shares will be issued in connection with the exercise of a Warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Cashless Exercise

Assuming the Warrant Stockholder Approval is obtained, if at the time a holder exercises its Warrants, a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act is not then effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Warrants.

Assuming the Warrant Stockholder Approval is obtained, a holder of Warrants may also provide notice and elect an "alternative cashless exercise" pursuant to which they would receive an aggregate number of shares equal to the product of (x) the aggregate number of shares of Common Stock that would be issuable upon a cash exercise of the Warrant and (y) 1.2.

Transferability

Subject to applicable laws, the Warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the Warrants to us together with the appropriate instruments of transfer.

Exchange Listing

There is no established trading market for the Warrants and we do not plan on applying to list the Warrants on The Nasdaq Capital Market any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions

If, at any time while the Warrants are outstanding, (1) we consolidate or merge with or into another corporation whether or not the Company is the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, or any of our significant subsidiaries, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of our Common Stock, (4) we consummate a securities purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding Common Stock, or (5) we effect any reclassification or recapitalization of our Common Stock or any compulsory exchange pursuant to which our Common Stock is converted into or exchanged for other securities, cash or property, or each, a "Fundamental Transaction;" provided, however, that the Merger and Asset Sale shall not be deemed a Fundamental Transaction, then upon any subsequent exercise of Warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as they would have been entitled to receive upon the occurrence of such Fundamental Transaction if they had been, immediately prior to such Fundamental Transaction, the holder of the number of shares of Common Stock then issuable upon exercise of those Warrants, and any additional consideration payable as part of the Fundamental Transaction. Notwithstanding the foregoing, in the event of a Fundamental

Transaction, the holders of the Warrants have the right to require us or a successor entity to redeem the Warrants for cash in the amount of the Black-Scholes Value (as defined in the Warrants) of the remaining unexercised portion of the Warrants on the date of the consummation of such Fundamental Transaction, concurrently with or within 30 days following the consummation of a fundamental transaction.

Rights as a Stockholder

Except by virtue of such holder's ownership of shares of our Common Stock or as otherwise set forth in the Warrants, the holder of a Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Warrant.

Pre-funded Warrants

The following summary of certain terms and conditions of the Pre-funded Warrants is not complete and is subject to, and qualified in its entirety by, the provisions of Pre-funded Warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Pre-funded Warrant for a complete description of the terms and conditions of the Pre-funded Warrants.

General

The term "pre-funded" refers to the fact that the purchase price of the Pre-funded Warrants in this offering includes almost the entire exercise price that will be paid under the Pre-funded Warrants, except for a nominal remaining exercise price of $0.001. The purpose of the Pre-funded Warrants is to enable investors that may have restrictions on their ability to beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding Common Stock following the consummation of this offering the opportunity to invest capital into the Company without triggering their ownership restrictions, by receiving Pre-funded Warrants in lieu of shares of our Common Stock which would result in such ownership of more than 4.99% (or, at the election of the holder, 9.99%), and receiving the ability to exercise their option to purchase the shares underlying the Pre-funded Warrants at a nominal price at a later date.

Form

The Pre-funded Warrants will be issued in certificated form as individual warrant agreements to the investors. You should review the form of Pre-funded Warrant, filed as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions applicable to the Pre-funded Warrants.

Exercisability

The Pre-funded Warrants are exercisable at any time after their original issuance. The Pre-funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the Pre-funded Warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Pre-funded Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-funded Warrants.

Duration and Exercise Price

The exercise price per whole share of our Common Stock purchasable upon the exercise of the Pre-funded Warrants is $0.001 per share of Common Stock. The Pre-funded Warrants will be immediately exercisable and may be exercised at any time until the earlier of (x) the Pre-funded Warrants are exercised in full and (y) the consummation of the Merger.

Cashless Exercise

If, at any time after the issuance of the Pre-funded Warrants, the holder exercises its pre-funded warrants and a registration statement registering the issuance of the shares of Common Stock underlying the Pre-funded Warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of Common Stock underlying the Pre-funded Warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of Common Stock determined according to a formula set forth in the Pre-funded Warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the Pre-funded Warrants to the holders.

Transferability

Subject to applicable laws, the Pre-funded Warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the Pre-funded Warrants to us together with the appropriate instruments of transfer.

Exchange Listing

There is no established trading market for the Pre-funded Warrants and we do not plan on applying to list the Pre-funded Warrants on The Nasdaq Capital Market any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions

If, at any time while the Pre-funded Warrants are outstanding, a Fundamental Transaction occurs (the Merger and Asset Sale shall not be deemed a Fundamental Transaction), then upon any subsequent exercise of pre-funded warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as they would have been entitled to receive upon the occurrence of such Fundamental Transaction if they had been, immediately prior to such Fundamental Transaction, the holder of the number of shares of Common Stock then issuable upon exercise of those pre-funded warrants, and any additional consideration payable as part of the Fundamental Transaction.

Rights as a Stockholder

Except by virtue of such holder's ownership of shares of our Common Stock or as otherwise set forth in the Pre-funded Warrants, the holder of a Pre-funded Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Pre-funded Warrant.

Placement Agent's Warrants

We have agreed to issue to the placement agent (or its permitted assignees) warrants to purchase a number of shares of Common Stock equal to 5.0% of the total number of Units being sold in this offering. The placement agent's warrants will be substantially similar to the Warrants issued to the purchasers hereunder except that the exercise price will be $[ ] per share (being equal to 120% of the public offering price of each Unit in this offering). Such warrant will be subject to FINRA Rule 5110(e)(1) in that, except as otherwise permitted by FINRA rules, for a period of 180 days from the commencement of sales of this offering, the warrant shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person except as permitted by FINRA Rule 5110(e)(2). See the form of placement agent's warrant filed as an exhibit hereto for a complete description of the terms of the placement agent's warrants. The placement agent's warrants and the shares of Common Stock underlying the placement agent's warrants are being registered on the registration statement of which this prospectus is a part.

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR HOLDERS OF OUR COMMON STOCK, WARRANTS AND PRE-FUNDED WARRANTS

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our units, consisting of our common stock or pre-funded warrants and common warrants acquired in this offering. The common warrants are referred to in this section as the "Warrants." The pre-funded warrants are expected to be treated in a manner similar to common stock. See "Income Tax Treatment of Pre-Funded Warrants." This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended, referred to as the Code, existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or IRS, with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, or Warrants, or that any such contrary position would not be sustained by a court.

We assume in this discussion that the shares of our common stock or Warrants will be held as capital assets (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the Medicare contribution tax, the alternative minimum tax and does not deal with state or local taxes, U.S. federal gift and estate tax laws, except as specifically provided below with respect to non-U.S. holders, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances. This discussion also does not address the special tax rules applicable to particular holders, such as:

- financial institutions;
- brokers or dealers in securities;
- tax-exempt organizations;
- pension plans;
- regulated investment companies;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- insurance companies;
- controlled foreign corporations, passive foreign investment companies, or corporations that accumulate earnings to avoid U.S. federal income tax; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities or persons who hold our common stock or Warrants through partnerships or other entities which are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock or Warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock or Warrants through a partnership or other pass-through entity, as applicable.

This discussion of U.S. federal income tax considerations is for general information purposes only and is not tax advice. Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock and Warrants.

For the purposes of this discussion, a "U.S. Holder" means a beneficial owner of our common stock or Warrants that is for U.S. federal income tax purposes (a) an individual citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons

(within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock or Warrants that is not a U.S. Holder or a partnership for U.S. federal income tax purposes.

Income Tax Treatment of Pre-Funded Warrants

Although not entirely free from doubt, a pre-funded warrant would more likely than not be treated as common stock for U.S. federal income tax purposes and a holder of pre-funded warrants therefore should generally be taxed in the same manner as a holder of a share of our common stock, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the shares of common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the shares of common stock received upon exercise, increased by the exercise price of $0.0001 per share. Each prospective investor is urged to consult its tax advisors regarding the tax risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes and the discussion below, to the extent it pertains to shares of our common stock, is generally intended also to pertain to pre-funded warrants.

Allocation of Purchase Price of the Unit

For U.S. federal income tax purposes, each unit will be treated as an "investment unit" consisting of one share of common stock and a warrant to acquire one share of our common stock. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the unit is purchased by the holder. This allocation of the purchase price for each unit will establish the holder's initial tax basis for U.S. federal income tax purposes in the share of common stock and the Warrant included in each unit. The separation of the share of common stock and the Warrant included in each unit should not be a taxable event for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding the allocation of the purchase price for a unit.

Tax Considerations Applicable to U.S. Holders

Exercise and Expiration of Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a Warrant. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a Warrant equal to the exercise price of the Warrant, increased by the U.S. Holder's adjusted tax basis in the Warrant exercised (as determined pursuant to the rules discussed above). The U.S. Holder's holding period in the shares of our common stock acquired on exercise of the Warrant will begin on the date of exercise of the Warrant, and will not include any period for which the U.S. Holder held the Warrant.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of Warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of Warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a Warrant described in the preceding paragraph. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of Warrants.

The lapse or expiration of a Warrant will be treated as if the U.S. Holder sold or exchanged the Warrant and recognized a capital loss equal to the U.S. Holder's tax basis in the Warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to and Distributions on Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the Warrants, or an adjustment to the exercise price of the Warrants, may be treated as a constructive distribution to a U.S. Holder of the Warrants if, and to the extent that, such adjustment has the

effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). An adjustment made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property to the holders of Warrants. In certain circumstances, if we were to make a distribution in cash or other property with respect to our common stock after the issuance of the Warrants, then we may make a corresponding distribution to a Warrant holder. The taxation of a distribution received with respect to a Warrant is unclear. It is possible such a distribution would be treated as a distribution (or constructive distribution), although other treatments are possible. For more information regarding the tax considerations related to distributions, see the discussion below regarding "Distributions." U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to the Warrants and any distributions with respect to the Warrants.

Distributions

As discussed above, we currently anticipate that we will retain future earnings, if any, to finance the growth and development of our business and do not intend to pay cash dividends in respect of our common stock in the foreseeable future. In the event that we do make distributions on our common stock to a U.S. Holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a U.S. Holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock as described below under the section titled "— Disposition of Our Common Stock or Warrants." Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be eligible for taxation as "qualified dividend income" and therefore may be taxable at rates applicable to long-term capital gains. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. Dividends received by a corporate U.S. Holder will be eligible for the dividends-received deduction if the U.S. Holder meets certain holding period and other applicable requirements.

Disposition of Our Common Stock or Warrants

Upon a sale or other taxable disposition of our common stock or Warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the common stock or Warrants. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder's holding period for the common stock or Warrants exceeds one year. Long-term capital gains recognized by non-corporate U.S. Holders will be subject to reduced tax rates. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock or Warrants should consult their own tax advisors regarding the tax treatment of such losses.

Information Reporting and Backup Reporting

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on the common stock and Warrants and to the proceeds of a sale or other disposition of common stock and Warrants paid by us to a U.S. Holder unless such U.S. Holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. Holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against the U.S. Holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS. U.S. Holders should consult their own tax advisors regarding their qualification for exemption from information reporting and backup withholding and the procedure for obtaining such exemption.

Tax Considerations Applicable To Non-U.S. Holders

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined herein) with respect to their ownership and disposition of our securities issued pursuant to this offering. All prospective non-U.S. holders of our securities should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our securities.

Exercise and Expiration of Warrants

In general, a Non-U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon the exercise of Warrants into shares of common stock. The U.S. federal income tax treatment of a cashless exercise of Warrants into our common stock is unclear. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of Warrants. The expiration of a Warrant will be treated as if the Non-U.S. Holder sold or exchanged the Warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the Warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a Warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

Certain Adjustments to and Distributions on Warrants

As described under "— U.S. Holders — Certain Adjustments to and Distributions on Warrants," an adjustment to the Warrants could result in a constructive distribution to a Non-U.S. Holder, which would be treated as described under "Distributions" below, and the tax treatment of distributions on the Warrants is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the Non-U.S. Holder. Non-U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to and distributions on the Warrants.

Distributions

As discussed above, we currently anticipate that we will retain future earnings, if any, to finance the growth and development of our business and do not intend to pay cash dividends in respect of our common stock in the foreseeable future. In the event that we do make distributions on our common stock to a Non-U.S. Holder, those distributions generally will constitute dividends for U.S. federal income tax purposes as described in "— U.S. Holders — Distributions".

Any distribution (including constructive distributions) on our common stock that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the holder's conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a Non-U.S. Holder that are effectively connected with the holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent

establishment or fixed base that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to the applicable withholding agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments. See also the sections below titled "— Backup Withholding and Information Reporting" and "— Foreign Accounts" for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

Disposition of Our Common Stock or Warrants

Subject to the discussions below under the sections titled "— Backup Withholding and Information Reporting" and "— Foreign Accounts," a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock or Warrants unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business in the United States, and if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States; in these cases, the Non-U.S. Holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons, and if the Non-U.S. Holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the Non-U.S. Holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the Non-U.S. Holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder, if any; or
- our common stock constitutes a U.S. real property interest because we are, or have been at any time during the five-year period preceding such disposition (or the Non-U.S. Holder's holding period of the common stock, if shorter), a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the Non-U.S. Holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the Non-U.S. Holder held our common stock. Special rules may apply to the determination of the 5% threshold in the case of a holder of. Non-U.S. Holders are urged to consult their own tax advisors regarding the effect of holding on the calculation of such 5% threshold. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" (as defined in the Code and applicable regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. Non-U.S. Holders are urged to consult their own tax advisors regarding the U.S. federal income tax considerations that could result if we are, or become, a "U.S. real property holding corporation".

See the sections titled "— Backup Withholding and Information Reporting" and "— Foreign Accounts" for additional information regarding withholding rules that may apply to proceeds of a disposition of our common stock paid to foreign financial institutions or non-financial foreign entities.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is not a citizen or resident of the United States (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise. The foregoing may also apply. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal estate tax consequences of the ownership or disposition of shares of our common stock.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions (including constructive distributions) on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends (or constructive dividends) on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a Non-U.S. Holder, or otherwise establishes an exemption. Dividends paid to Non-U.S. Holders subject to withholding of U.S. federal income tax, as described above under the heading "Dividends," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a 30% withholding tax on dividends (including constructive dividends) on, and, subject to the discussion of certain proposed Treasury Regulations below, gross proceeds from the sale or other disposition of, our common stock if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a "foreign financial institution," the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a "foreign financial institution," the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section.

Withholding under FATCA generally applies only to payments of dividends (including constructive dividends) on our common stock. The U.S. Treasury has issued proposed Treasury Regulations which, if finalized in their present form, would eliminate the FATCA withholding tax on the gross proceeds of a sale or other disposition of our common stock or. In its preamble to such proposed Treasury Regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Prospective investors should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock or, and the possible impact of these rules on the entities through which they hold our common stock or, including, without limitation, the process and deadlines for

meeting the applicable requirements to prevent the imposition of this 30% withholding tax under FATCA. Under certain circumstances, a holder may be eligible for refunds or credits of the tax. Holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

THE PRECEDING DISCUSSION OF MATERIAL U.S. FEDERAL TAX CONSIDERATIONS IS FOR INFORMATION ONLY. IT IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK OR WARRANTS, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGES IN APPLICABLE LAWS.

PLAN OF DISTRIBUTION

Pursuant to a placement agency agreement, dated as of [ ], 2025, we have engaged Maxim Group LLC to act as our exclusive placement agent to solicit offers to purchase the securities offered by this prospectus. The placement agent is not purchasing or selling any securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use its "best efforts" to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to the rights and remedies available to all investors in this offering under federal and state securities laws, the investors which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. The placement agent may engage one or more subagents or selected dealers in connection with this offering.

The placement agency agreement provides that the placement agent's obligations are subject to conditions contained in the placement agency agreement.

The Units will be offered at a fixed price and are expected to be issued in a single closing. There is no minimum number of Units to be sold or minimum aggregate offering proceeds for this offering to close.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about [ ], 2025.

Placement Agent Fees, Commissions and Expenses

Upon the closing of this offering, we will pay the placement agent a cash transaction fee equal to 7.0% of the aggregate gross cash proceeds to us from the sale of the securities in the offering. In addition, we will reimburse the placement agent for certain of its accountable and out-of-pocket expenses incurred in connection with this offering, including the placement agent's legal fees, and actual travel and reasonable out-of-pocket expenses, in an amount not to exceed $125,000. If this offering is not completed, we have agreed to reimburse the placement agent for its actual expenses in an amount not to exceed $50,000.

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us, assuming the sale of all Units in this offering and the exercise of all issued Pre-funded Warrants.

	Per Unit Consisting of One Share of Common Stock and One Warrant	Per Unit Consisting of One Pre-funded Warrant and One Warrant	Total
Public offering price	$	$	$
Placement agent fees (7.0%)	$	$	$
Proceeds, before expenses, to us	$	$	$

We estimate that the total expenses of the offering payable by us, including registration and filing fees, printing fees and legal and accounting expenses, but excluding the placement agent fees above, will be approximately $[ ] million. This figure includes, among other things, the placement agent's expenses (including the fees, costs and expenses for the placement agent's legal counsel) that we have agreed to reimburse.

Placement Agent's Warrants

We have agreed to issue to the placement agent (or its permitted assignees) warrants to purchase a number of shares of Common Stock equal to 5.0% of the total number of Units being sold in this offering. The placement agent's warrants will be substantially similar to the Warrants issued to the purchasers hereunder except that the exercise price will be $[ ] per share (being equal to 120% of the public offering price of each Unit in this offering) and the warrants will expire the later of (i) twelve (12) days after date of Warrant Stockholder Approval and (ii) the earlier of (x) the closing date of the transaction contemplated by the Merger and (y) sixty (60) days after the date of Warrant Stockholder Approval or in no event later than five years from the commencement of sales of this offering. Such warrant will be subject to FINRA

Rule 5110(e)(1) in that, except as otherwise permitted by FINRA rules, for a period of 180 days from the commencement of sales of this offering, the warrant shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person except as permitted by FINRA Rule 5110(e)(2). See the form of placement agent's warrant filed as an exhibit hereto for a complete description of the terms of the placement agent's warrants. The placement agent's warrants and the shares of Common Stock underlying the placement agent's warrants are being registered on the registration statement of which this prospectus is a part.

Lock-Up Agreements

The Company has agreed that for a period of fifteen days from the Stockholder Approval Date, that neither the Company nor any subsidiary may, without the prior written consent of the placement agent (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any Common Stock or Common Stock equivalents or (ii) file any registration statement or prospectus, or any amendment or supplement thereto, subject to certain conditions and exceptions.

The Company's directors and officers shall enter into customary "lock-up" agreements in favor of the placement agent pursuant to which such persons and entities shall agree, for a period of fifteen days from the Stockholder Approval Date, that they shall neither offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any securities of the Company without the placement agent's prior written consent, subject to certain conditions and exceptions.

Tail

Upon the closing or termination (other than for cause as defined in FINRA Rule 5110(g)(5)(B)) of this offering, then if within twelve (12) months following such time, the Company, or any successor to or any subsidiary of the Company, completes any financing of equity, equity-linked or debt or other capital raising activity with, or receives any proceeds from, any of the investors contacted or introduced by the placement agent during period of engagement, then the Company or such successor or subsidiary will pay the placement agent upon the closing of such financing or receipt of such proceeds the compensation equivalent to 7.0% of the gross proceeds of such financing and a warrant equal to 5% of the securities purchased in such financing.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the placement agent may be required to make for these liabilities.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent acting as principal. Under these rules and regulations, the placement agent (i) may not engage in any stabilization activity in connection with our securities and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Determination of Offering Price

The actual public offering price of the securities we are offering was negotiated between us, the placement agent and the investors in the offering based on the trading of our Common Stock prior to the offering, among other things. Other factors considered in determining the public offering price of the securities

we are offering include our history and prospects, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, the general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent. In connection with the offering, the placement agent or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus in electronic format, the information on the placement agent's website and any information contained in any other website maintained by the placement agent is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent in its capacity as placement agent and should not be relied upon by investors.

Certain Relationships

The placement agent and its affiliates have and may in the future provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

On June 19, 2024, the Company retained Maxim to provide financial advisory services to the Company's Board of Directors in evaluating the Vyome proposal and in rendering an opinion to the Board as to the fairness of the Exchange Ratio in the Merger from a financial perspective to the Company's stockholders. Maxim was paid $300,000 related to these services in June and July 2024.

Maxim has also acted as an exclusive M&A advisor to the Company pursuant to an agreement dated September 20, 2023, as amended on June 19, 2024. Pursuant to that agreement, the Company paid Maxim certain cash fees in November 2023 and has agreed to pay Maxim upon the consummation of the Merger a fixed cash fee of $1.5 million.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Equiniti Trust Company, LLC.

Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "RSLS."

Selling Restrictions

Other than in the United States, no action has been taken by us or the placement agent that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published, in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia. No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering.

This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons (the Exempt Investors) who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Brazil. The offer of securities described in this prospectus will not be carried out by means that would constitute a public offering in Brazil under Law No. 6,385, of December 7, 1976, as amended, under the CVM Rule (Instrução) No. 400, of December 29, 2003. The offer and sale of the securities have not been and will not be registered with the Comissão de Valores Móbilearios in Brazil. The securities have not been offered or sold, and will not be offered or sold in Brazil, except in circumstances that do not constitute a public offering or distribution under Brazilian laws and regulations.

Canada. The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31 103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33 105 Underwriting Conflicts (NI 33 105), the placement agent is not required to comply with the disclosure requirements of NI 33-105 regarding conflicts of interest in connection with this offering.

Cayman Islands. No invitation, whether directly or indirectly, may be made to the public in the Cayman Islands to subscribe for our securities.

European Economic Area. In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any securities may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined

in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by us or any placement agent of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Hong Kong. The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our shares may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to "professional investors" within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the SFO and any rules made thereunder.

Israel. This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

The People's Republic of China. This prospectus may not be circulated or distributed in the PRC and the shares may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Switzerland. The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of securities.

Taiwan. The securities have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the securities in Taiwan.

United Kingdom. This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000, or the FSMA) as received in connection with the issue or sale of our Common Stock in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to our Common Stock in, from or otherwise involving the United Kingdom.

RESHAPE AND VYOME UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

On July 8, 2024, ReShape, Vyome, and Merger Sub, entered into the Merger Agreement ("Merger"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions specified therein, Merger Sub shall be merged with and into Vyome, with Vyome surviving as a subsidiary of ReShape.

At the Effective Time of the Merger, each Vyome Share issued and outstanding immediately prior to the Effective Time (other than the shares that are owned by ReShape, Vyome, or Merger Sub and shares that will be subject to a put-call option agreement with certain stockholders of Vyome located in India) will be converted into the right to receive a number of fully paid and non-assessable ReShape Shares according to an Exchange Ratio determined at least 10 calendar days prior to the ReShape Special Meeting that will result in the holders of such Vyome Shares, together with holders of Vyome securities convertible into Vyome Shares, owning 91.62% of the outstanding ReShape Shares on a fully-diluted basis immediately after the Effective Time.

The Merger Agreement provides that, at the Effective Time, each outstanding stock optionor other equity award to purchase capital stock of Vyome will be converted into equity awards to purchase a number of ReShape Shares equal to the number of shares of Vyome Common Stock issuable upon exercise of such Vyome equity award multiplied by the Exchange Ratio, with an exercise price, in the case of warrants and stock options, equal to the exercise price of such Vyome option divided by the Exchange Ratio. The exercise price and number of shares will be determined in a manner consistent with the requirements of Section 409A, and as applicable, Section 424(a) of the Internal Revenue Code, and the applicable regulations promulgated thereunder.

Simultaneously with the execution of the Merger Agreement, ReShape entered into the Asset Purchase Agreement with Biorad ("Asset Sale"). Pursuant to the Asset Purchase Agreement, and subject to the satisfaction or waiver of the conditions specified therein, ReShape will sell substantially all of its assets (excluding cash) to Biorad, and Biorad will assume substantially all of ReShape's liabilities, for a purchase price of $5.16 million in cash, subject to adjustment based on ReShape's actual accounts receivable and accounts payable at the closing compared to such amounts as of March 31, 2024. Biorad is party to a previously disclosed exclusive license agreement, dated September 19, 2023, with ReShape for ReShape's Obalon® Gastric Balloon System. The proforma financials below included the anticipated impact the Asset Sale might have on our combined financial information.

Simultaneously with the execution of the Merger Agreement, ReShape, Vyome, and Vyome's wholly-owned subsidiary Vyome Therapeutics Limited ("Vyome India") entered into agreements with certain existing accredited investors, pursuant to which the investors have agreed to purchase of approximately $7.3 million in securities of ReShape, Vyome and Vyome India (the "Concurrent Financing"). As part of the Concurrent Financing, certain accredited investors have agreed to purchase up to $6.05 million in shares of common stock of the combined company immediately following completion of the Merger. The price per share for the common stock of the Combined Company will be calculated as a 30% discount to the price per share of the common stock for the agreed upon valuation of the combined company obtained by dividing (i) the sum of $130,000,000 and ReShape Net Cash by (ii) the sum of Total ReShape Outstanding Shares and Vyome Merger Shares. Simultaneously with the execution of the subscription agreements, Vyome entered into a securities purchase agreement with each investor pursuant to which Vyome issued to each investor a convertible promissory note in the principal amount equal to approximately 5% of such investor's total agreed upon investment amount, which convertible notes will bear interest at 8% per annum and immediately prior to completion of the Merger will convert into a number of shares of common stock of the combined company equal to 100% of the outstanding principal and interest of the Note divided by the price per share of common stock to be purchased in the financing as set forth above. ReShape and the investors are executing and delivering the subscription agreements in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, and contemporaneously with the sale of the shares of common stock will execute and deliver a registration rights agreement in substantially the form attached to the subscription agreement.

The pro forma ownership percentages of the ReShape and Vyome stockholders of the Combined Company of 8.38% and 91.62%, respectively, subject to adjustment as described in this prospectus, is prior

to taking into account the Concurrent Financing. Therefore, the actual ownership percentages will be different following the completion of the Concurrent Financing and, because certain of the investors in the Concurrent Financing are existing Vyome stockholders, the actual ownership percentage of the ReShape stockholders will be decreased compared to that of the Vyome stockholders after the closing of the Concurrent Financing.

The following unaudited pro forma condensed combined financial statements have been prepared to illustrate the estimated effects of the Merger. The ReShape and Vyome unaudited pro forma combined balance sheet data assume that the Asset Sale and the Merger closed on January 1, 2024, and combine the ReShape and Vyome historical balance sheets at September 30, 2024. The ReShape and Vyome unaudited pro forma condensed combined statements of operations data assume that the Asset Sale and the Merger closed as of January 1, 2023 and combine the historical results of operations of ReShape and Vyome for the nine months ended September 30, 2024, and the year ended December 31, 2023. The unaudited pro forma condensed combined financial information was prepared pursuant to the rules and regulations of Article 11 of SEC Regulation S-X, as amended.

The Merger is accounted for as a reverse recapitalization under U.S. GAAP since ReShape will have nominal operations and assets at the time of the closing of the Merger. Vyome was determined to be the accounting acquirer based upon the terms of the Merger and other factors including (i) holders of such Shares, together with holders of Vyome securities convertible into Vyome Shares are expected to own 91.62% of the outstanding ReShape Shares on a fully-diluted basis immediately after the Effective Time, (ii) Vyome will hold substantially all of the board seats of the combined company and (iii) Vyome's management will hold all key positions in the management of the combined company.

The unaudited pro forma condensed combined financial statements are based on and should be read in conjunction with both Vyome and ReShape Management's Discussion and Analysis of Financial Condition and Results of Operations and Vyome and ReShape's financial statements and related notes appearing elsewhere in this prospectus.

The unaudited pro forma condensed combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the consolidated financial position or results of operations that would have been realized had the Merger occurred as of the dates indicated, nor is it meant to be indicative of any future consolidated financial position or future results of operations that the Combined Company will experience. The unaudited pro forma condensed combined financial statements combine the historical statements of ReShape and Vyome, the Concurrent Financing undertaken, and reflects the impact of the sale of substantially all of ReShape's assets and liabilities to BioRad, for the period on a pro forma basis along with the Merger and related transactions, summarized below. The pro forma adjustments included in the accompanying unaudited pro forma condensed combined financial statements are based on currently available data and assumptions that management of ReShape believes are reasonable.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
FOR THE YEAR ENDED DECEMBER 31, 2023
(Amounts in thousands, except per share data)

	Historical						
	12 months ended						
	December 31, 2023	December 31, 2023	Vyome Pro Forma Adjustments Note 6		ReShape Pro Forma Adjustments Note 6		Total Pro Forma Adjustments	Pro Forma Combined
	Vyome	Reshape						
Revenue	$ 416	$ 8,678	$ —		$ (8,678)	B	$ (8,678)	$ 416
Cost of revenue	133	3,130	—		(3,130)	B	(3,130)	133
Gross profit	283	5,548	—		(5,548)		(5,548)	283
Operating expenses:								
Selling, General and Administrative	756	17,872	—		(17,872)	B	(17,872)	756
Research and development	294	2,315	—		(2,315)	B	(2,315)	294
Impairment of long-lived assets	—	777	—		(777)	B	(777)	—
Gain on sale of assets and consumption of liabilities, net	—	—	—		—		—	—
(Gain) loss on disposal of assets, net	—	(33)	—		33	B	33	—
Total operating expenses	1,050	20,931	—		(20,931)		(20,931)	1,050
Operating loss	(767)	(15,383)	—		15,383		15,383	(767)
Other expense (income), net:								
Interest expense, net	165	(26)	(165)	E	26	B	(139)	—
(Gain) Loss on extinguishment of debt	2	—	—		—		—	2
Gain on changes in fair value of liability warrants	—	(3,878)	—		3,878	B	3,878	—
Gain on change in fair value of convertible debt	(214)	—	214	E	—		214	—
Gain on foreign currency exchange	—	(22)	—		22	B	22	—
Other, net	—	(122)	—		122	B	122	—
Loss before income tax provision	(720)	(11,335)	(49)		11,335		11,286	(769)
Income tax benefit	—	52	—		(52)	B	(52)	—
Net loss attributable to common shareholders	$ (720)	$ (11,387)	$ (49)		$ 11,387		$ 11,338	$ (769)
Net loss per share – basic and diluted:	$ (0.38)	$ (110.87)						$ (0.12)
Weighted-average shares used to compute net loss per share attributable to ordinary shareholders	1,893,120	102,707						6,182,415

See accompanying Notes to Unaudited Pro Forma Condensed Combined Financial Information.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET
As of September 30, 2024
(Amounts in thousands, except per share data)

	September 30, 2024 Vyome	September 30, 2024 ReShape	Vyome Pro Forma Adjustments Note 5		ReShape Pro Forma Adjustments Note 5		Total Pro Forma Adjustments Note 5	Pro Forma Combined
ASSETS								
Current assets:								
Cash and cash equivalents	$ 49	$ 743	$ 5,571	D, G	$ (468)	A	$ 5,103	$ 5,895
Restricted cash	—	100	—		(100)	B	(100)	—
Accounts and other receivables (net of allowance for doubtful accounts)	—	1,344	—		(1,344)	B	(1,344)	—
Inventory	—	2,934	—		(2,934)	B	(2,934)	—
Prepaid expenses and other current assets	86	217	—		(217)	B	(217)	86
Total current assets	135	5,338	5,571		(5,063)		508	5,981
Property and equipment, net	74	43	—		(43)	B	(43)	74
Operating lease right-of-use assets	68	177	—		(177)	B	(177)	68
Deferred tax asset, net	—	28	—		(28)	B	(28)	—
Goodwill	—	—	—		—		—	—
6	314	—	—		—		—	314
Other assets	763	29	—		(29)	B	(29)	763
TOTAL ASSETS	$ 1,354	$ 5,615	$ 5,571		$ (5,340)		$ 231	$ 7,200
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERENCE SHARES, REDEEMABLE CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' (DEFICIT) EQUITY AND SHAREHOLDERS' (DEFICIT) EQUITY								
Accounts payable	$ 847	$ 2,105	$ —		$ (2,105)	B	$ (2,105)	$ 847
Accrued and other liabilities	963	1,643	—		(1,643)	B	(1,643)	963
Warranty liability, current	—	163	—		(163)	B	(163)	—
Put / call liability	—	—	—		—		—	—
Liabilities to be settled in equity	—	—	—		—		—	—
Due to affiliates	98	—	—		—		—	98
Convertible debt – current portion	2,305	—	(2,305)	E	—		(2,305)	—
Operating lease liabilities, current	27	114	—		(114)	B	(114)	27
Total current liabilities	4,240	4,025	(2,305)		(4,025)		(6,330)	1,935
Debt, noncurrent portion	1,183	—	(1,183)	E	—		(1,183)	—
Operating lease liabilities, noncurrent	41	77	—		(77)	B	(77)	41
Warranty liability, noncurrent	—	—	—		—		—	—
Deferred income taxes	—	—	—		—		—	—
Common stock warrant liability	—	26	—		(26)	B	(26)	—
Other long-term liabilities	—	—	—		—		—	—
TOTAL LIABILITIES	5,464	4,128	(3,488)		(4,128)		(7,616)	1,976
Commitments and contingencies								
Preferred stock	47,419	—	(47,419)	E, F	—		(47,419)	—
Common stock	2	—	—		6	C	6	8
Additional paid-in capital	3,439	642,518	58,178	D, E	(641,646)	C	(583,468)	62,489
Accumulated other comprehensive loss	236	(88)	—		88	B	88	236
Accumulated deficit	(55,206)	(640,943)	(1,700)	G	640,340	C	638,640	(57,509)
Total shareholders' (deficit) equity / stockholders' (deficit) equity	(4,110)	1,487	9,059		(1,212)		7,847	5,224
Total liabilities, redeemable convertible preference shares and stock, and shareholders' (deficit) equity and stock	$ 1,354	$ 5,615	$ 5,571		$ (5,340)		$ 231	$ 7,200

See accompanying Notes to Unaudited Pro Forma Condensed Combined Financial Information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
FOR THE NINE MONTHS ENDED SEPTEMBER 30,2024
(Amounts In thousands, except per share date)

	Historical						
	9 months ended						
	September 30, 2024	September 30, 2024	Vyome Pro Forma Adjustments Note 5		ReShape Pro Forma Adjustments Note 5		Total Pro Forma Adjustments Note 5	ProForma Combined
	Vyome	Reshape						
Revenue	$ 196	$ 6,201	$ —		$(6,201)	B	$(6,201)	$ 196
Cost of revenue	64	2,463	—		(2,463)	B	(2,463)	64
Gross profit	132	3,738	—		(3,738)		(3,738)	132
Operating expenses:								
Selling, General and Administrative	740	8,482	—		(8,482)	B	(8,482)	740
Research and development	256	1,282	—		(1,282)	B	(1,282)	256
Impairment of long-lived assets	—	—	—		—		—	—
Gain on sale of assets and consumption of liabilities, net	—	—	—		—		—	—
(Gain) loss on disposal of assets, net	—	—	—		—		—	—
Total operating expenses	996	9,764	—		(9,764)		(9,764)	996
Operating loss	(864)	(6,026)	—		6,026		6,026	(864)
Other expense (income), net:								
Interest expenses, net	153	(13)	(153)	E	13	B	(140)	—
(Gain) Loss on extinguishment of debt	—	(429)	—		429	B	429	—
Gain on changes in fair value of liability warrents	—	(46)	—		46	B	46	—
Gain on changes in fair value of convertible debt	240	—	(240)	E	—		(240)	—
Gain of foreign currency exchange	—	(10)	—		10	B	10	—
Other, net	(2)	(193)	—		193	B	193	(2)
Loss before income tax benefit	(1,255)	(5,335)	393		5,335		5,728	(862)
Income tax benefit	—	34	—		(34)	B	(34)	—
Net loss attributable to common shareholders	$ (1,255)	$ (5,369)	$ 393		$ 5,369		$ 5,762	$ (862)
Net loss per share – basic and diluted:	$ (0.66)	$ (11.94)						$ (0.14)
Weighted- average shares used to compute net loss per share attributable to ordinary shareholders	1,893,120	449,614						6,182,415

See accompanying Notes to Unaudited Pro Forma Condensed Combined Financial Information.

Notes to the Unaudited Pro Forma Condensed Combined Financial Statements

1. Description of the Merger

On July 8, 2024, ReShape, Vyome, and Merger Sub, entered into the Merger Agreement. Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions specified therein, Merger Sub shall be merged with and into Vyome, with Vyome surviving as a subsidiary of ReShape.

At the Effective Time of the Merger, each Vyome Share issued and outstanding immediately prior to the Effective Time (other than the shares that are owned by ReShape, Vyome, or Merger Sub and shares that will be subject to a put-call option agreement with certain stockholders of Vyome located in India) will be converted into the right to receive a number of fully paid and non-assessable ReShape Shares according to an Exchange Ratio determined at least 10 calendar days prior to the ReShape Special Meeting that will result in the holders of such Vyome Shares, together with holders of Vyome securities convertible into Vyome Shares, owning 91.62% of the outstanding ReShape Shares on a fully-diluted basis immediately after the Effective Time.

The Merger Agreement provides that, at the Effective Time, each outstanding stock option or other equity award to purchase capital stock of Vyome will be converted into equity awards to purchase a number of ReShape Shares equal to the number of shares of Vyome Common Stock issuable upon exercise of such Vyome equity award multiplied by the Exchange Ratio, with an exercise price, in the case of stock options, equal to the exercise price of such Vyome option divided by the Exchange Ratio. The exercise price and number of shares will be determined in a manner consistent with the requirements of Section 409A, and as applicable, Section 424(a) of the Internal Revenue Code, and the applicable regulations promulgated thereunder.

In connection with the transactions contemplated by the Merger Agreement ReShape entered into an agreement with a majority of the holders of its outstanding Series C Preferred Stock pursuant to which the holders of the Series C Preferred Stock agreed, subject to and contingent upon the completion of the Merger and the Asset Sale, to reduce the liquidation preference of the Series C Preferred Stock from $26.2 million to the greater of (i) $1 million, (ii) 20% of the purchase price paid for the Asset Sale and (iii) the excess of ReShape's actual net cash at the effective time of the Merger over the minimum net cash required as a condition to the closing of the Merger as set forth in the Merger Agreement and described below (the "Series C Amendment"). Under the terms of the Series C Amendment, the Series C Preferred Stock would automatically terminate at the effective time of the Merger and would be paid the agreed upon reduced liquidation preference.

In the Merger, ReShape stockholders will continue to own and hold their existing ReShape Shares. Each ReShape restricted stock unit award that is outstanding and unvested immediately prior to the Effective Time, shall become fully vested as of immediately prior to, and contingent upon, the Effective Time. Each ReShape stock option that is outstanding, whether vested or unvested, immediately prior to the Effective Time shall be canceled and terminated without any payment.

2. Basis of Presentation

The unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11, as amended by SEC Final Rule Release No. 33-10786, *Amendments to Financial Disclosures About Acquired and Disposed Businesses*. In accordance with Release No. 33-10786, the unaudited condensed combined pro forma balance sheet and statements of operations reflect transaction accounting adjustments, as well as other adjustments deemed to be directly related to the Proposed Transactions, irrespective of whether or not such adjustments are deemed to be recurring.

Reverse Stock Split

On September 23, 2024, at the commencement of trading, ReShape effected a 1-for-58 reverse stock split. Accordingly, all share and per share amounts presented in the accompanying pro forma financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split. No fractional shares were issued in connection with the reverse stock split.

For accounting purposes, Vyome is considered to be the acquiring company and the Merger will be accounted for as a reverse recapitalization of ReShape by Vyome because, at the time of the Merger, ReShape is expected to have nominal assets and operations as a result of the closing of the Asset Sale.

Under reverse recapitalization accounting, the financial statement of the combined entity will represent a continuation of the financial statements of Vyome. No goodwill or intangible assets will be recognized. The unaudited pro forma condensed combined financial information of Vyome reflects the operations of the acquirer for accounting purposes together with the shares held by the stockholders of the legal acquirer and the issuance of the shares to be held by the accounting acquirer. The pro forma adjustments represent management's best estimates and are based upon currently available information and certain assumptions that management believes are reasonable under the circumstances.

The unaudited pro forma information is not necessarily indicative of what the Combined Company's financial position or results of operations would have been had the Merger been completed on the dates indicated. In addition, the unaudited pro forma condensed combined financial information does not purport to project the future financial position or operating results of the Combined Company.

There were no material transactions between ReShape and Vyome during the periods presented in the unaudited pro forma condensed combined financial statements.

3. Accounting Policies and Reclassification Adjustments

The accounting policies used in the preparation of this unaudited pro forma condensed combined financial information are those set out in Vyome's consolidated financial statements as of and for the year ended December 31, 2023, and as of and for the nine months ended September 30, 2024. Based on Vyome management's assessment to date, the accounting policies of ReShape are similar in all material respects to Vyome's accounting policies.

The Combined Company may, as a result, identify additional differences between the accounting policies of the two companies which, when conformed, could have a material impact on the combined consolidated financial statements.

Certain reclassifications have been made ReShape's financial statements to conform to classifications used by Vyome.

4. Share Issuances

At the Effective Time, each Vyome Share (other than the shares that are owned by ReShape, Vyome, or Merger Sub and shares that will be subject to a put-call option agreement with certain Indian stockholders of Vyome and its' subsidiary in India) will be converted into the right to receive a number of ReShape Shares, according to a ratio determined at least 10 days prior to the ReShape Special Meeting that will result in the holders of such Vyome Shares owning 91.62% of the outstanding Combined Company Shares immediately after the effective time of the Merger, subject to adjustment based on ReShape's net cash is greater than or less than $5 million. Based on the number of shares outstanding as of September 13, 2024, and assuming ReShape's net cash is equal to $975,000, the Exchange Ratio would be equal to .54 ReShape Shares for each share of Vyome common stock outstanding or underlying the Vyome preferred stock, without giving effect to the proposed reverse stock split of ReShape Shares described in this proxy/information statement- prospectus. However, that estimated Exchange Ratio is not final and is subject adjustment based on the actual shares outstanding, and ReShape's actual net cash, as of the Determination Date.

Because the exact number of ReShape Shares that will be issued in exchange for each Vyome Share will not be determined until a later date, the market value of the Merger Consideration that Vyome stockholders will receive will depend both on the number of ReShape Shares to be issued and the price per ReShape Share at the Effective Time. The exact number of ReShape Shares to be Vyome and the market price per ReShape Share will not be known at the time of the ReShape Special Meeting and may be less or more than the current market price or the market price at the time of the ReShape Special Meeting.

Based on the closing price per share of ReShape Shares on The Nasdaq Capital Market on November 8, 2024 of $5.60, the date on which the assumed Exchange Ratio of .5432 ReShape Shares for each Vyome Share was calculated, the estimated value of each Vyome Share in the Merger would be approximately $[*[•] x Exchange Ratio*]. The exact dollar value of the ReShape Shares that the Vyome stockholders and the ReShape stockholders will hold upon consummation of the Merger will not be known at the time of the ReShape Special Meeting and may be greater than, the same as or less than the current market price of ReShape Shares at the time of the ReShape Special Meeting. The market price of the ReShape Shares is subject to general price fluctuations in the market for publicly traded equity securities and has experienced volatility in the past and may vary significantly from the date of the ReShape Special Meeting. As a result of these fluctuations, the value of the Merger Consideration will also vary. For example, based on the range of closing prices of ReShape Shares during the period from July 8, 2024, the last trading day before public announcement of the Merger, through [•], 2025, of $[•] to $[•], the assumed Exchange Ratio represented a value ranging from a low of $[[•] *x Exchange Ratio*] to a high of $[[•] *x Exchange Ratio*] for each ReShape Share.

The following table shows the shares outstanding pre- and post-Merger for purposes of this pro forma financial statement, as adjusted for the share exchange ratio.

	Shares Issued	Entitlement Shares in Combined Company to honor put/call option agreement using Vyome-USA and Vyome-India shares	Fully Diluted shares outstanding
		(in thousands)	(in thousands)
Shares of Reshape, post reverse stock split	588,270	—	588,270
Shares to be issued to former Vyome debtholders, common and preferred shareholders, penny warrants (which will be exercised and convert to common shares prior to Merger date) for participation in Concurrent financing – a portion of which are subject to the put/call option agreement	3,687,895	715,677	4,403,572
Underlying entitlement of common Shares in the Combined company for former Indian resident shareholders for participation in Concurrent Financing by putting money in Vyome-India- subject to the put/call option agreement	—	696,854	696,854
	4,276,165	1,412,531	5,688,696
Shares to be issued in Concurrent Financing only for those amounts that come at merger closing in Combined company and the entitlement shares thru a put/call option agreement using the shares of Vyome's subsidiary as a result of such an investment at merger closing in Vyome's India subsidiary	424,405	69,314	493,719
Post-merger, proforma shares outstanding in Combined company and Vyome subsidiary in India	4,700,570	1,481,845	6,182,415

The following table shows the split fully diluted shares outstanding for purposes of this pro forma financial statement:

	Shares
	(in thousands)
Post-merger Vyome stock options outstanding	1,331,678
Post-merger, proforma shares outstanding	6,182,415
Fully diluted shares outstanding	7,514,093

As a result of the conversion of the Vyome Convertible Debt, preferred stock and Bridge Financing to common shares prior to the Merger, Vyome will have an estimated 3.6 million common shares outstanding and 0.7 million shares subject to the put/call option described below.

ReShape completed a 1-for-58 reverse stock split prior to the Merger such that approximately 588 thousand common shares will be outstanding. In connection with the Merger and pursuant to the Exchange ratio, ReShape will issue approximately 3.7 million shares to former Vyome shareholders. At the Merger date, there will be 0.7 million entitled shares of the Combined Company which are subject to put/call option agreement using Vyome shares owned by certain Indian resident shareholders. At the Merger date, there will be 0.7 million entitled shares of the Combined Company which are subject to put/call Option agreement using Vyome' subsidiary shares owned by certain Indian resident shareholders. At the Merger date, there will be Vyome stock options outstanding for the purchase of approximately 1.3 million shares of common stock.

Post Merger, the combined company is expected to issue approximately 0.42 million shares of common stock from the Concurrent Financing, raising expected gross proceeds of approximately $6.1 million. Also, as part of Concurrent financing for the investments made by certain India resident shareholders in Vyome's subsidiary in India, there will be 0.07 million entitled shares of the Combined Company which are subject to put/call option agreement using this investment-related shares in Vyome's subsidiary in India. The actual value of the Merger Consideration will be subject to change based on the final Exchange Ratio determined as of the Determination Date and the underlying market price of the ReShape Shares. As a result, changes in Reshape's stock price will impact the market value of the ReShape Shares to be issued in the Merger. This is also indicated below through the sensitivity analysis performed using the hypothetical change in the closing price of ReShape Shares to assess the impact on the number of shares issued to holders of Vyome Shares and the number of ReShape Shares underlying the ReShape preferred stock and warrants to be issued in exchange for Vyome Series C Preferred Stock and warrants, respectively, as part of Merger Consideration on the Effective Date.

Based on ReShape's closing share price of $5.60 on November 8, 2024, the value of shares to be issued in connection with the Merger will be approximately $28,652. This amount reflects the following:

- Shares to be issued to former Vyome debtholders, common and preferred shareholders, penny warrants (which will be exercised and convert to common shares prior to Merger date) for participation in Concurrent financing — a portion of which are subject to the put/call option agreement.
- Underlying entitlement of common shares in the combined company for former Indian resident shareholders for participation in Concurrent Financing by putting money in Vyome-India- subject to the put/call option agreement

The value of shares to be issued post Merger, in connection with the Concurrent Financing, will be approximately $2,765. This amount reflects the following:

- Shares to be issued in Concurrent Financing only for those amounts that come at merger closing in combined company and the entitlement shares thru a put/call option agreement using the shares of Vyome's subsidiary as a result of such an investment at merger closing in Vyome's India subsidiary

This amount will change based on fluctuations in the market price of ReShape common shares. Vyome believes that a 10% fluctuation in market price of ReShape common shares is reasonably possible based on historical volatility, and the potential effect on the value of shares to be issued would be:

	ReShape's share price	Value of shares to be issued in connection with Merger	Value of shares to be issued post Merger
		(in thousands)	
As presented	$5.60	$28,562	$2,765
10% increase	6.16	31,419	3,041
10% decrease	5.04	25,706	2,488

5. Notes to Unaudited Pro Forma Condensed Combined Balance Sheet — Pro Forma Adjustments

ReShape Pro Forma Adjustments:

A: The proceeds from the sales of the ReShape operating business to BioRad will be used primarily pay costs related to Merger costs, employee costs and other matters. A portion of the remaining cash available

after payment of such expenses will be paid to the ReShape Series C preferred shareholders and left in the combined company subject to various considerations, including whether ReShape undertakes a bridge loan. The below tables reflect adjustments to cash and cash equivalents as of December 31, 2023 and September 30, 2024, based upon the assumption that no additional bridge loan is undertaken:

December 31, 2023:

	Amount (in thousands)
Change in control bonus – paid to Preferred Series C shareholders[(1)]	$(1,000)
Contingent success fee[(2)]	(1,500)
Cash paid for third party expenses[(3)]	(540)
Consideration to ReShape Series C Preferred Stockholders[(4)]	(3,911)
Cash paid for PTO and Severance[(5)]	(1,620)
Cash paid for D&O Tail[(6)]	(773)
Cash proceeds from Asset Sale to Biorad[(7)]	5,160
Total pro forma adjustment to cash and cash equivalents	$(4,184)

September 30, 2024:

	Amount (in thousands)
Change in control bonus – paid to Preferred Series C shareholders[(1)]	$(1,000)
Contingent success fee[(2)]	(1,500)
Cash paid for third party expenses[(3)]	(540)
Consideration to ReShape Series C Preferred Stockholders[(4)]	(195)
Cash paid for PTO and Severance[(5)]	(1,620)
Cash paid for D&O Tail[(6)]	(773)
Cash proceeds from Asset Sale to Biorad[(7)]	5,160
Total pro forma adjustment to cash and cash equivalents	$ (468)

(1) Reflects payment of $1.0 million to Preferred Series C shareholders related to change in control payout under the Series C purchase agreements.

(2) Reflects contingent success fee to be paid to Maxim upon completion of transaction.

(3) Reflects costs paid related to the Merger transaction. Amounts include fairness opinion, legal, and audit fees.

(4) Reflects liquidation of the Series C Preferred Stock in the amount of the excess of the actual "net cash" of ReShape at the closing of the Merger over the minimum net cash required as a condition to the closing of the Merger.

(5) Reflects severance, termination, or similar payments due to certain current and former employees.

(6) Reflects costs for the "tail" D&O insurance policies paid in accordance with the Merger Agreement.

(7) Reflects cash proceeds from the Asset Sale to Biorad ReShape will sell substantially all of its assets (excluding cash) to Biorad, and Biorad will assume substantially all of ReShape's liabilities, for a purchase price of $5.16 million in cash.

B: Reflects the elimination of ReShape's assets and liabilities as of December 31, 2023, and September 30, 2024 (excluding the $275,000 cash required to remain in the Company under the Merger Agreement) to the standalone operating entity, as Vyome is not assuming any of ReShape's assets or liabilities in the transaction. These adjustments reflect the impact of the sale of substantially all of ReShape's assets and liabilities to BioRad, and the elimination of the operating accounts of ReShape as a result of the Asset Sale.

C: To record the (i) elimination of ReShape's accumulated deficit $(641.0M); (ii) issuance of entitlement Shares in Combined Company to honor put/call option agreement and issuance of common stock to Vyome as part of merger (5,594,145 shares); (iii) transaction costs of $5.0 million associated with the Merger recorded to accumulated deficit. Such costs include contingent success fee ($1.5M), fairness opinion, legal, and audit fees ($0.8M), severance, termination, or similar payments due to certain current and former employees ($1.9M), and costs for the "tail" D&O insurance policies paid in accordance with the Merger Agreement ($0.8M); (iv) elimination of ReShape's additional paid-in capital ($643.0M); transaction costs of $1.3 million associated with the Merger recorded to additional paid-in capital.

Vyome Pro Forma Adjustments:

D: Through August 2024, Vyome continued its compulsory note payable bridge offering ("Bridge Financing"), which could be raised prior to the Merger. The term of these Bridge Financing notes is similar to the convertible notes issued by Vyome since 2020 and may be issued by either the Vyome US parent company or the Vyome subsidiary in India. Through September 30, 2024, the Vyome US parent company raised approximately $273,000 of these Bridge Financing notes which, along with accrued interest, will convert immediately prior to the Merger at a 25% discount to the 30% discount to the valuation determined through the Merger. The Bridge Financing notes issued by the Vyome subsidiary in India of approximately $86,000 have the same terms and are also subject to a "put/call option" — see discussion below. Approximately $82,000 of further commitments under such facilities are expected to be received after September 30, 2024. Immediately prior to the Merger, all but the notes subject to the put/call option from such Bridge Financing notes were converted into shares of common stock of Vyome.

In July 2024, Vyome commenced a debt and equity offering ("Concurrent Financing") of up to $10 million to be issued by Vyome. It's subsidiary in India and the combined company immediately after completion of Merger. The investors in the Concurrent Financing were able to invest in a one-year 8% compulsory convertible note issued by either Vyome or the Vyome subsidiary in India or shares of either the combined company or Vyome's subsidiary entity in India. Certain investors also received a warrant to purchase shares of the combined company's common stock at $0.001 per share. The Company has received commitments of approximately $6.1 million of the combined company common stock and has received commitments of approximately $1.0 million of common stock of the Vyome subsidiary in India and are also subject to a "put/call option" — see discussion below — under such Concurrent Financing.

E: Vyome's outstanding principal amount of their Convertible Notes including any unpaid accrued interest shall automatically convert in whole into Vyome's common shares immediately prior to the Merger date at a conversion price equal to the assumed pre-Merger valuation per share multiplied by 0.75 and then multiplied by 70%. Since this conversion is deemed to have happened at the beginning of each period presented, the recorded interest expense and changes in the fair value of the convertible notes is eliminated from the presentation of the pro forma results of operations.

F: Each share of Vyome's preferred stock is mandatorily convertible into shares of Vyome common stock at the conversion price as defined in the shareholders' agreement immediately prior to the Merger date. However, certain India-based shareholders will not convert their preferred shares into common shares due to regulatory restrictions. Instead, they will receive shares subject to the put/call option — see below.

The shares issued by Vyome subsidiary in India and certain shares owned by Indian resident shareholders are subject to put and call option agreements whereby the Combined Company can call the shares at the quoted market value on such date called by the combined company, or the shareholders can put their shares to the combined company either for exchange, subject to certain conditions, of the equivalent number of combined company shares or for a specified amount of cash subject to explicit approval of the board of directors of the combined company.

G: Vyome's estimated transaction costs for the Merger related expenses is $1.7 million

6. Notes to Unaudited Pro Forma Condensed Combined Statement of Operations — Pro Forma Adjustments

E: — Refer to Note E above for adjustments related to Vyome's convertible debt.

7. Pro Forma Weighted Average Shares (Basic and Diluted)

Basic net loss per share of common stock is computed by dividing net loss by the weighted average number of vested shares of common stock outstanding during the period. Diluted net income per share of common stock is computed by dividing net income by the weighted average number of common and dilutive common-equivalent shares outstanding during each period. The exchanged Vyome stock options were excluded from the calculation of weighted average dilutive shares of common stock because their inclusion would have been anti-dilutive.

The below tables reflect the Pro Forma earnings per share computation as of December 31, 2023, and September 30, 2024:

	Pro Forma For the Year Ended December 31, 2023
	(in thousands)
Numerator for basic earnings per share calculation:	
Pro Forma loss (for basic and diluted EPS)	$ (769)
Denominator for basic and diluted earnings per share calculation:	
Weighted-average ReShape's outstanding shares	588,270
Issuance of common stock to Vyome as part of merger	5,594,145
Pro Forma weighted average shares (basic and diluted)	6,182,415
Pro Forma earnings per share (basic and diluted)	$ (0.12)

	Pro Forma For the Nine Months Ended September 30, 2024
	(in thousands)
Numerator for basic earnings per share calculation:	
Pro Forma loss (for basic and diluted EPS)	$ (862)
Denominator for basic and diluted earnings per share calculation:	
Weighted-average ReShape's outstanding shares	588,270
Issuance of common stock to Vyome as part of merger	5,594,145
Pro Forma weighted average shares (basic and diluted)	6,182,415
Pro Forma earnings per share (basic and diluted)	$ (0.14)

VYOME INFORMATION

In this section, "our", "we", "Company" or "Vyome" refers to Vyome Therapeutics, Inc.

Overview

We are an innovation-driven healthcare company bridging the fast-growing US-India innovation corridor. We have spent the last decade developing research-driven assets in the immuno-inflammation sector. Our vision is to be a holding group of several healthcare assets and businesses that leverage the increasingly "special relationship" between the US and India, a relationship that manifests itself in the talent flowing from India to the US, as well as the growing collaboration between the world's largest healthcare market (the US) and one of the world's fastest growing major healthcare market (India). Our origin story begins with a Massachusetts Institute of Technology (MIT) and All India Institute of Medical Services (AIIMS) educated scientific founder setting up research in India, building a business in the US, and partnering with an Indian-origin American-born capital markets entrepreneur he met at MIT reflects our alignment with what we believe is a generational opportunity immediately in front of us. We believe we would be the first venture-backed Indo-US biopharma company to list on the Nasdaq.

We believe the US-India special relationship offers a once-in-a-generation opportunity, particularly in the healthcare sector. Whether it is pharmaceutical R&D, medical devices, Artificial Intelligence (AI), or telemedicine, we believe there is a wide-ranging opportunity set to leverage the talent and market opportunities in both countries which we believe is worth hundreds of billions of dollars.

Some of the opportunities Vyome intends to explore in the US-India corridor including:

- Pharmaceutical R&D — existing business line, large opportunity to expand
- Medical devices — there is a growing opportunity for innovation in medical devices to come from India; there is also a growing Indian market where local companies could collaborate with American behemoths
- Artificial intelligence — there are many applications of AI in healthcare; with the US and India being two of the most vibrant AI ecosystems in the world, there will be numerous cross-border opportunities
- Telemedicine — in a post-COVID world, we believe there is an increasing opportunity to leverage skilled, lower cost medical talent in India to service other parts of the world

As we navigate the wider opportunity set, our lens for executing on any potential transactions will be strictly one of accreting shareholder value. We intend to become a platform through which investors can access the growing US-India healthcare opportunity set in an efficient and accretive manner.

Today, we are primarily a clinical-stage pharmaceutical company with multiple assets, focused on immune and inflammatory disorders. According to the National Institute of Health, nearly 125 million people in the U.S. live with some form of chronic inflammatory disease. According to Fortune Business Insights, immuno-inflammation diseases present a market opportunity that is over a $100 billion and growing rapidly. We believe our differentiated development strategy and our access to world-class talent can result in transformative medicines that significantly improve the life of patients suffering from such debilitating diseases and clear near-term drivers of value for shareholders.

The classical model of drug development is capital and time-intensive, but we have built our initial set of assets by disrupting this classical model by (i) leveraging the US-India talent and cost arbitrage, (ii) selecting rare and unmet immune-inflammatory conditions as the first disease targets, and (iii) repositioning approved drugs for novel use through local application, which together, potentially allows us to shorten the development timeline to approval, and minimize the risks associated with new approvals, while generating intellectual property. We have extensive networks in India, which offers the opportunity to access innovation at a value arbitrage, lowering costs of development and value creation. We believe that by initially targeting rare conditions allows us to potentially access certain regulatory benefits, including the Orphan Drug Act of 1983, and lower number of patients in clinical trials, which can potentially reduce

costs of development. Taken together, we believe our model brings a unique risk/return proposition for shareholders by balancing cost efficiencies and value creation.

Our programs

Thus far, we have developed three programs:

- **VT-1953** — Our lead program, VT-1953, is a dual DNA Gyrase/Topoisomerase inhibitor and immunomodulator in a topical gel formulation. An eye drop with the same active agent as in VT-1953 is approved by the U.S. FDA (NDA#22-308) for the treatment of bacterial conjunctivitis. We have reformulated the active agent in a topical gel for application on skin. We have tested VT-1953 topical gel for safety and efficacy in extensive preclinical studies and in four clinical trials, including phase 1 and phase 2 studies in US, with over 400 patients with moderate to severe inflammatory acne and an investigator initiated study in patients with malodorous malignant fungating wound (MFW), a debilitating immune-inflammatory condition present in approximately 5 – 14% of advanced cancer patients in the United States, according to the "The Microbiome, Malignant Fungating Wounds, and Palliative Care" article by Frontiers. Based on interim analysis, VT-1953 was found to decrease malodor in MFW by over 75% and pain by 50%. We plan to conduct pivotal studies for VT-1953 for treatment of symptoms of malignant fungating wound. We believe that VT-1953's potential to treat symptoms of this rare and unmet medical condition can be transformative for cancer patients and their caregivers. Based on its mechanism of action, we believe VT-1953 can be expanded in the future to a broad range of potentially large indications, including inflammatory acne, diabetic foot ulcers, and pressure sores.
- **VT-1908** — Our next development program VT-1908, topical eye drop is an inosine 5′-monophosphate dehydrogenase enzyme inhibitor, for treating immunoinflammatory conditions of the eye. We plan to develop VT-1908 for treating anterior uveitis as the first indication, especially in patients where steroid use is contraindicated. Uveitis is a rare immune-inflammatory condition, where activated immune cells attack the uvea of the eye which can lead to blindness. VT-1908 exhibited biological activity statistically comparable to steroid use in an animal model of uveitis. For example, in a study published in 2022 in the journal Eye (The Scientific Journal of the Royal College of Ophthalmologists), investigators from Massachusetts Eye Research and Surgery Institution reported that "monotherapy appears to be an effective and safe treatment in pediatric autoimmune uveitis". Similarly, another clinical study, the MySTRI study published in 2020 in the journal Eye, concluded "mycophenolate sodium is an effective steroid-sparing drug for the treatment of corticosteroid-refractory non-infectious inflammatory uveitis (CRU)". We are currently conducting pre-clinical studies and manufacturing activities for VT-1908 in anticipation of enabling clinical trials by the second half of 2025. The FDA has not approved mycophenolate or mycophenolate sodium to treat patients with uveitis and would need to review clinical trial data in order to determine that these drugs are safe and effective to treat uveitis. Based on the mechanism of action, we believe the use of VB-1908 can be extended to a broad range of potential indications, including post-cataract surgery inflammation, scleritis, and blepharitis as a growth strategy, and has the potential to replace steroid use in the eye.
- **Molecular Replacement Therapy** — Our innovation engine has also generated a molecular replacement therapy ("MRT") platform, with the potential of improving the efficacy of existing antifungal agents. We have signed a collaboration and license agreement with Sun Pharma Laboratories Limited ("Sun Pharma"), to develop and commercialize these next-generation antifungal products which incorporate our MRT technology. We intend to continue to leverage our existing pipeline and platform to actively explore and evaluate potential value-creating partnering opportunities.

Our beginnings and vision

Vyome Biosciences Private Limited ("VBPL") was originally co-founded in New Delhi, India by Dr. Shiladitya Sengupta, a professor of medicine and of health sciences and technology at Harvard Medical School and Massachusetts Institute of Technology, and Dr. Rajesh Gokhale, an immunologist at the National Institute of Immunology in New Delhi and the current secretary of the Department of Biotechnology of the Government of India. The vision of VBPL was to foster innovation in medical drug development for global impact in a cost-efficient manner by leveraging the best of talents in the US-India

corridor. India had made significant strides in the information technology space, and our founders believed that the ecosystem was ripe to pioneer a similar leap-frogging in the bio-technology and healthcare space.

Our Chief Executive Officer, Venkat Nelabhotla, joined VBPL as the Co-founder and CEO. Mr. Nelabhotla is an alumnus of Indian Institute of Management, Ahmedabad. He worked as CEO & Executive Director of Emami Ltd and as Senior Vice President of Aurobindo Pharma Limited.

Dr. Sengupta graduated from the All India Institute of Medical Sciences (AIIMS), which is regularly recognized as the leading medical school in India. At AIIMS, Dr. Sengupta specialized in medical pharmacology or the science of drugs. While at AIIMS, he had seen the creativity needed to treat patients in a resource-poor setting, and has leveraged that creativity in developing the programs at VBPL. Dr. Sengupta further trained at the University of Cambridge as a Nehru Scholar, and at Massachusetts Institute of Technology, where he integrated advanced science and technology in medical research. Our scientific approach is built on this scientific rigor and advanced technology, which together with the learnings from a resource-poor setting offers a power engine for innovation, differentiation and cost-efficiency.

Dr. Gokhale is an alumnus of the Indian Institute of Science, the top-ranked science institution in India, and then trained as a chemical biologist at Stanford University.

As part of a corporate restructuring, the drug development business of VBPL was transferred in December 2018 to Vyome Therapeutics Limited, our subsidiary, which was formed in India. We were incorporated as a Delaware company in 2017.

Vyome raised its first American capital from Krishna Gupta and his venture capital firm in 2016 after initially meeting Dr. Sengupta at MIT nearly a decade earlier. Mr. Gupta believed in the science as well as the wider opportunity to build companies together at the intersection of the US and India. This bridge to the US was to locate close to clinical development sites and facilitate interactions with the regulatory agencies and to have access to talent and capital. We believe this unique straddling of the best of both worlds, leveraging the best of R&D talent and the highest quality standard of clinical trials creates value with high capital efficiency.

We believe the US and India relations are seeing a transformation driven by geopolitical and economic alignments and Vyome intends to build its platform by taking advantage of the same. In a November 2023 press release, the US Department of State reaffirmed, *'The relationship between the United States and India is one of the most strategic and consequential of the 21st century.'* We believe we are uniquely poised to leverage this emerging special relationship, especially as the influence of China is curtailed. Not only has billions of dollars of international capital flowed out of China according to the article "Foreign Investors Pull Record Amount of Money From China" by Bloomberg, laws such as the BIOSECURE Act limit the ability of US companies to contract with biotechnology companies with ties to Chinese government.

We have and will continue to build our team to reflect this evolving geopolitical relationship. Ambassador Frank Wisner, a former US Ambassador to India, will join the Combined Company's board upon consummation of the Merger. Our Indian subsidiary's board is chaired by Dr. Ramesh Mashelkar, a fellow of the Royal Society (UK) and member of National Academy of Sciences of United States. Dr. Mashelkar served as the science advisor to the prime minister of India, was the director general of Council of Scientific and Industrial Research (CSIR) labs, the largest network of government research laboratories in India, and has served on the board of Reliance Industries, Tata Motors, and other reputed companies. Investors in Vyome includes Dr. Ranjan Pai, a well-known Indian businessman who owns Manipal Hospitals, the second- largest hospital chain in India, and Sanjeev Taparia, who built and sold one of the largest women's health companies in the world. We believe such networks give us a tremendous competitive advantage in this rapidly evolving geopolitical market opportunity. We aim to leverage this network to source deals and grow organically.

Immuno-Inflammatory Diseases

A well-functioning immune system forms the foundation of human health, impacting every biological process and organ system of the body. The immune system acts as the defense against any threats, both external, such as viruses and bacteria, and internal, such as cancer. It also plays a critical role in normal homeostasis, facilitating routine cell turnover and removing cellular debris, such as in normal healing.

However, an overactive immune system can also get inappropriately directed to attack normal cells and tissues to cause autoimmune diseases and inflammation, which is deleterious for one's health. There are over 80 diseases and conditions where the immune system gets overactivated. According to the National Institute of Health, nearly 125 million people in the US live with some form of chronic inflammatory disease. Immuno-inflammatory diseases are an active area of research and development, and a market opportunity that is over $100 billion and growing rapidly.

We aim to establish a leadership position in this emerging market by taking a pragmatic approach of focusing on unmet rare inflammatory conditions in the near term, which we believe can open doors to other disease opportunities in the future.

Our Strategy

Our goals are to: (1) treat and improve the quality of life of patients with serious immuno-inflammatory conditions; (2) build a cost-efficient innovation model to disrupt the currently expensive drug development process; and (3) commercialize products through strategic business development of our assets and in-licensing of new assets. To achieve our goals, we intend to:

- *Aggressively move our lead program, VT-1953, through clinical development, including a pivotal study for the treatment of symptoms of malignant fungating wound.* By focusing on the treatment of symptoms, which we anticipate will resolve within 14 days with treatment with VT-1953, we can run a short clinical trial. Typical pivotal oncology trials, especially for rare and unmet indications, require small patient sample sizes. For example, as reported in the Journal of American Medical Association (JAMA), a study on the Characteristics of Clinical Trials to Support Approval of Orphan vs Nonorphan Drugs for Cancer concluded "Compared with pivotal trials used to approve nonorphan cancer drugs, pivotal trials for recently approved orphan drugs for cancer were more likely to be smaller and to use nonrandomized, unblinded trial designs and surrogate end points to assess efficacy". Pivotal trials for orphan drugs enrolled fewer patients exposed to the drug per study than those for nonorphan drugs (median, 96 versus 290). Furthermore, we will leverage the India-US network to accelerate our clinical recruitment while lowering costs. We plan to continue a hands-on engagement with all trial sites to ensure timely clinical trial execution and high-quality data collection.
- *Pragmatically build the pipeline with laser-focus on selecting rare and unmet medical conditions that can be addressed using a clinically-approved drug.* We deploy a differentiated strategy of drug development. In the classical drug discovery model, thousands of drugs are screened of which one makes it to finish-line as an approved drug, making it a highly inefficient and costly process. We start with an active molecule in an FDA-approved product and map its mechanism of action to the mechanism driving a rare (orphan) and unmet disease condition. This strategy (a) cuts down on development time as we do not need to invent a drug from scratch; (b) reduces the risk of the drug failing due to toxicity, (c) potentially offers the advantages of the Orphan Drug Act, and (d) reduces the cost of clinical development as the number of patients in a pivotal study are lower than for non-orphan drugs as described above.
- *Opportunistically evaluate strategic and commercial opportunities to maximize the value of our product candidates by aggressively leveraging our US-India footprint to create value and reduce costs.* We will aggressively pursue business and investment opportunities across both countries, while setting high bars for quality and value creation. For example, we have entered into a license and collaboration agreement with Sun Pharma to commercialize our MRT technology-based products in India. We intend to opportunistically seek partnerships in Europe, Canada and other markets, and retain the US market for commercialization. We may acquire other products or product candidates that we believe can make a substantial impact on immune-inflammatory diseases and yield high user satisfaction.
- *Continue to strengthen our intellectual property portfolio.* We have developed and continue to expand our portfolio of intellectual property for the treatment of immuno-inflammatory diseases. Our key programs have patent protection until 2034 and in some cases until 2043 due to a robust intellectual property portfolio underpinned by issued patents or patent applications. We will continue to file additional patents as we generate data, including from clinical studies. If one of our product

candidates is approved, we believe that it could be the first FDA-approved product for an orphan indication and would then be eligible for seven years of exclusivity in the United States. As of the date of this prospectus, we have not yet received orphan drug designation for any of our programs. To date, we have not had any meetings with the FDA regarding Phase 3 trial protocols or regarding obtaining orphan drug designation, and although we plan to receive orphan drug designation, there is no guarantee that such designation will be granted. We plan to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates by filing for additional patents or other applicable intellectual property protection covering new or enhanced proprietary technology, including new methods of use, formulations and dosing regimens. We also rely on regulatory frameworks, trademarks, trade secrets, know-how, and continuing technological innovation and may consider in-licensing opportunities to develop and maintain our proprietary position.

- *Continue to build an experienced team with the capabilities of building a leading healthcare-focused innovation company.* We have built a leadership team with extensive experience across successful life science and consumer product companies and who have developed and commercialized multiple biopharmaceutical products and well-known consumer-focused brands. Our leadership team is complemented by a team of leading medical advisors across the immune-inflammation fields. We intend to time the expansion of our commercial capabilities to coincide with the expected timing of any regulatory approval.

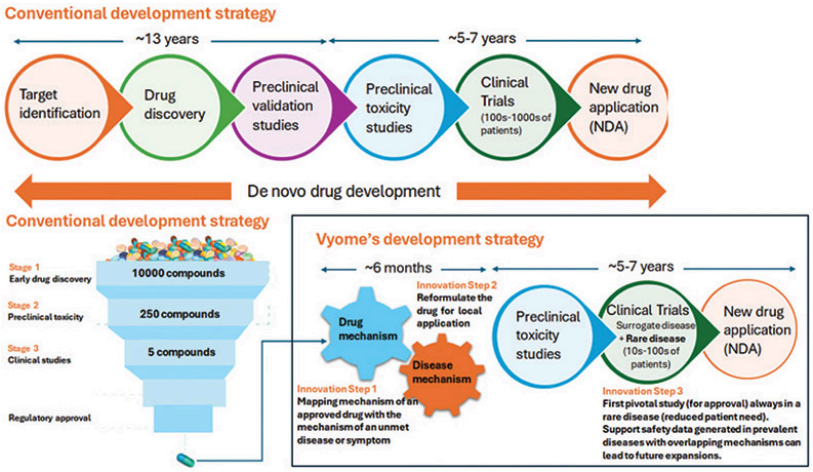
Vyome's differentiated development engine

The classical de novo drug discovery process involves many different stages, is time-consuming and expensive. Typically, it can be divided into four main stages: (1) early drug discovery, (2) pre-clinical phase, (3) clinical phases, and (4) regulatory approval **(*See* Figure 1).**

- The early discovery process involves many different actions and testing to identify and optimize potential leads that elicit a desirable effect on a specific biological target implicated in a disease, in the hopes of treating it. It involves target identification and validation, high throughput screening or high content screening, hit identification, assay development and screening, Hit-To-Lead (H2L), lead generation and optimization, and *in vivo* and *in vitro* Assays.
- The second stage is the pre-clinical phase, where the leads identified during the early drug discovery phase are refined, optimized, and extensively tested in animal or alternative models. The aim is to provide sufficient evidence of safety and efficacy before clinical trials in humans can begin.
- Clinical trials are composed of three phases: In Phase 1, the tolerance and safety of the drug candidate is tested in a very small group of healthy or diseased subjects, usually 20 to 80; Phase II studies are performed to examine the effectiveness, tolerability, and dosage in a larger group. For this, the dosage form is first developed. Phase II studies usually include 100 to 500 adult patients in the study; in Phase 3, the drug is tested on thousands of patients to see whether the effectiveness and safety can be confirmed in many different patients.
- The final stage is regulatory approval for a molecule that is both safe and effective.

At each step of development, there is a significant risk of failure, and as a result, of the thousands of molecules that one starts with in early drug discovery, only one makes it as a drug, making the classical drug discovery model inefficient, time-consuming and extremely expensive (See **Figure.1**).

Figure 1. Vyome's differentiated drug development model.



At Vyome, we start from a molecule that is the active component of an already FDA-approved product, shaving off years of expensive discovery and optimization **(See Figure 1)**. In our differentiated development strategy, we carefully analyze the mechanisms of action of the molecule, and then do an extensive survey of all diseases and disease symptoms that are mechanistically overlapping and therefore can be treated with the drug. This drug mechanism-disease mapping requires deep expertise and is our first innovative step allowing us to generate novel use IP, while avoiding the long-drawn out discovery process and risks of failure in those steps. The expertise needed to achieve the innovative first stage of drug development can act as a barrier to entry for competition.

We next select a rare indication that has no approved treatments as the target disease for development. In the United States, rare diseases (RDs) are statutorily defined as conditions that impact 200,000 individuals or less. As of February 2024, more than 30 million Americans are affected by a rare disease. At the same time, about 5% of rare diseases have a Food and Drug Administration (FDA)-approved treatment and less than 15% have at least one drug either in clinical development or that has demonstrated potential in treatment, diagnosis or prevention. We believe this offers a large blank slate to build a leadership position. We next reformulate the molecule in a topical form for local application to the disease site. This reformulation builds additional IP.

As compared to the classical drug development model, we believe our model to repurpose existing drugs for initial approval for orphan immune-inflammatory diseases offer the following regulatory advantages:

- Cost and Time Savings: Our model includes lower patient numbers in clinical trials. As compared to hundreds or thousands of patients needed for non-orphan indications, orphan indications require lesser number of patients for regulatory submissions for approval. There are some orphan diseases, where even 10 patients are hard to find. We have selected disease conditions where patients are readily available. For example, as reported recently in 2011 in the Journal of American Medical Association (JAMA), a study on the Characteristics of Clinical Trials to Support Approval of Orphan vs Nonorphan Drugs for Cancer concluded that "*Compared with pivotal trials used to approve nonorphan cancer drugs, pivotal trials for recently approved orphan drugs for cancer were more likely to be smaller and to use nonrandomized, unblinded trial designs and surrogate end points to assess efficacy." This study found that pivotal trials for orphan drugs enrolled fewer patients exposed to the drug per study than those for nonorphan drugs (median 96 v 290)*. Lower patient numbers can lower development cost compared with non-orphan indications. Orphan-designated drugs had a shorter FDA review time on average (1.6 years) than nonorphans that were approved as new molecular entities (2.2 years) (Seoane-Vezquez et al., 2008). Additionally, as noted in a 2012 article on approval of new agents after

phase II trials in the American Society for Clinical Oncology Educational Book, "*A confirmatory phase II trial, which need not be randomized if an active control is not available' (as is our case as there are no approved drugs), can provide sufficient evidence to convince regulatory authorities to grant accelerated approval, and the process can be completed in three years or less.*" To date, we have not had any meetings with the FDA regarding Phase 3 trial protocols or regarding obtaining orphan drug designation, and although we plan to receive orphan drug designation, there is no guarantee that such designation will be granted.

- Regulatory Support: The Orphan Drug Act provides special incentives to manufacturers who develop drugs to treat rare diseases, including grants to perform clinical trials, a 50% tax credit for clinical testing costs, and an exclusive right to market the drug for seven years after regulatory approval. Orphan drug manufacturers also receive waivers of drug application fees and may be eligible for faster review by the FDA. We will strive to get orphan indication status for our initial programs.
- Regulatory Advantages in Clinical Development: Safety data from clinical trials (in non-orphan indication settings) may expedite the development process, decreasing time to market and accelerating the timeline for potential treatments.

In parallel to focusing on rare immune-inflammatory diseases as our initial indications for drug development, we are also mapping non-orphan indications that mechanistically overlap with the orphan indication. For example, fungating wounds can be present in diabetic foot ulcers or pressure sores, and accordingly, we believe VT-1953, mechanistically should address the symptoms of these chronic wounds. According to JAMA, diabetic foot ulcers affect about 18.6 million people worldwide and 1.6 million in the US annually. Similarly, we believe VT-1908 can be extended from treating steroid-incompatible uveitis to treating immune-inflammation of the eye post-cataract surgery. We believe this opens the possibility for us to address larger indications and markets in the future. However, as discussed earlier, clinical trials for non-orphan indications generally take longer time and require larger number of patients, and we anticipate such development efforts will be driven through non-dilutive partnerships so as to achieve capital efficiencies.

Vyome's Product Portfolio

Leveraging the above strategy, we have built out a robust product portfolio (See **Figures 2.1 and 2.2**).

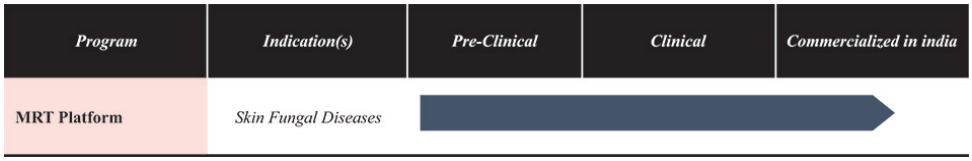
Figure 2.1 Pipeline for VT-1953, VT-1908 and VB-1953

Program	Indication(s)	Pre-Clinical	IND	Phase 1	Phase 2	Pivotal	Commercial
VT-1953	*Malodor symptom in MFW*						
VT-1908	*Steroid sparing Uveitis*						
VB-1953	*Inflammatory Acne*						

(1) VB-1953's CMC, Toxicology and clinical safety data will be cross referenced for the IND filing of VT-1953 program and the MFW Pivotal study.

(2) Geographic partnerships will be utilized for this indication.

Figure 2.2 Pipeline for MRT Platform



(3) Three antifungal products have been developed using the MRT platform and licensed to Sun Pharma for India rights. As MRT platform uses a GRAS (generally regarded as safe) compound, the commercialized product could be directly tested in patients and not subjected to the traditional IND/

NDA route of development. Two of three such products are clinically tested with positive results in India, and Sun Pharma have commercialized these products. The MRT platform is being leveraged to add more products to the pipeline. When any of these new products include a pharmaceutically-regulated agent, the classical regulatory IND/NDA path needs to be followed.

The Combined Company currently expects to use the approximately $6.90 million in cash, cash equivalents, and marketable securities immediately after the completion of the Merger for up to one year and after deducting estimated transaction expenses as follows:

- approximately $2.75 million for continued research and development towards regulatory work and pivotal trial of VT-1953 for the therapeutic indication of treating malodor in malignant fungating wounds;
- approximately $1.00 million for continued advancement of VT-1908 into IND filing and Phase 1/2 trial; and
- the remainder for general corporate purposes.

The Company had determined to deprioritize the allocation of capital resources to its other programs and will pursue partnerships for its anti-inflammatory acne program and continue to leverage its MRT platform through its partnership with Sun Pharma and other partners.

The specific allocation of the expected cash, cash equivalents, and marketable securities immediately after the completion of the Merger towards specific programs will depend on, among other things, results from the Combined Company's research and development efforts for each program, the timing and success of its preclinical and clinical studies and the timing and outcome of regulatory submissions. Further, the amounts and timing of actual expenditures will depend on numerous factors, including the progress of preclinical development efforts, operating costs, and other factors described under "*Risk Factors*" beginning on page 24 of this proxy/information statement-prospectus. The expected use of proceeds represents current intentions based on present plans and business conditions. As of the date of this proxy statement/prospectus, the Combined Company cannot predict with complete certainty all of the particular uses for the expected cash that will be available upon the closing of the Merger or the actual amounts that it will spend on the uses set forth above. For more information, see "*Vyome Management's Discussion and Analysis of Financial Condition And Results Of Operations — Expected Use of Proceeds*" beginning on page 262 of this proxy/information statement-prospectus.

Program 1- VT-1953 — Topical gel for treating malodor malignant fungating wound (MFW)

Malignant fungating wounds (MFW) is a non-healing wound that occurs when cancer breaks through the skin, causing tissue necrosis resulting in the area becoming infected and inflamed. Although considered a rare condition, which offers the opportunity to access the regulatory advantages of orphan drug status, MFW afflicts approximately 5 – 14% of patients with advanced cancer. It is estimated that in 2025, there will be over six hundred and fifty thousand patients (650,000) living with advanced cancer in the US alone, and over ten million worldwide.

MFWs may arise from any type of malignant tumor, but the common primary sites are breast, head, neck, kidney, lung, ovary, colon, penis, skin, bladder, sarcomas, leukemia and lymphoma. Unfortunately, MFW is extremely distressing to patients given the high burden of symptoms, including extreme malodor, heavy exudate, bleeding, severe pain, leading to feeling of shame, low self-esteem, and social isolation (See **Figure 3**). In a report, Piggin and Jones, described the meaning of living with a malignant fungating wound from the perspective of five women, in that it caused immense distress, represented a huge new challenge and changed relationships with family and friends.

The management of symptoms is the mainstay of treatment for MFW. In a survey of nurses, 48% identified malodor as the main challenge, followed by pain and exudate control. In a study, 14 nurses, four patients and one care giver, reported MFW as an intense and unforgettable experience with most of the distress caused by malodor. This symptom has been described as "*odor is a constant day-to-day symptom of the patient, causing nausea and unleashing the progressive worsening of their nutritional status, in addition to afflicting the people with whom they interact, or even health professionals through direct contact*". The malodor

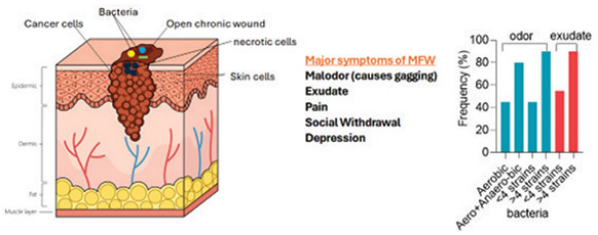
associated with MFWs has a significant negative effect on quality of life (QoL) and often inflicts a sense of shame due to the pervasive and pungent smell. Patients report that a reduction in the distressing experience of odor and pain enabled them to live more positively with the wound. Therefore, an effective treatment for malodorous MFW can be transformative for patients.

Current treatment options for MFW

The fetid odor associated with MFW is attributable to a combination of factors such as necrotic tissues and bacteria colonizing the wound. Bacteria produce malodorous molecules, which tend to linger and can cause vomiting, and together with debris from necrotic cells can induce tissue damage, inflammation and pain.

There are currently no FDA-approved treatments for MFW or for symptoms of malodorous malignant fungating wounds. Patients are managed using old obsolete and suboptimal agents, such as metronidazole, aromatic oils, camphor, honey- or silver-coated dressings. Metronidazole is widely used topically off label. However, metronidazole poses an occupational health risk as it is a mutagen. More importantly, it is effective only against strict anaerobic bacteria, whereas, recent clinical studies have revealed that MFW wounds are predominantly colonized with aerobic bacteria (and facultative anaerobes), with an average of 3.6 species of aerobes (and facultative anaerobes) to 1.7 species of anaerobes per patients. Some of the common aerobes (and facultative anaerobes) in MFW are *Staphylococcus, Pseudomonas, Corynebacterium, Streptococcus, Proteus, Escherichia, Enterococcus*, and others. While treatment of malodorous MFW with metronidazole reduces anerobic bacteria, the aerobes (and facultative anaerobes) remained unchanged after treatment. Recent studies have shown that both aerobic (such as Proteus, Klebsiella, Pseudomonas, Staphylococci) and anaerobic (Bacteroides, Clostridium, etc.) bacteria are responsible for malodor. Indeed, over 40% of patients with only aerobic bacterial colonization of MFW exhibit malodor. Additionally, bacterial load correlates with increased odor, exudates, and pain (See **Figure 3**). Taken together, an effective treatment of the symptoms of malodorous MFW needs a therapeutic agent that has potent activity against both anaerobic and aerobic bacteria. In addition, such a treatment needs to inhibit the inflammation due to cellular debris and bacterial metabolites.

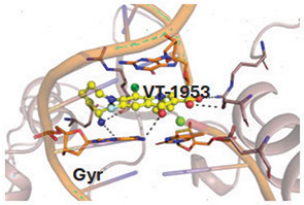
Figure. 3. Mechanistic analysis of MFW symptoms



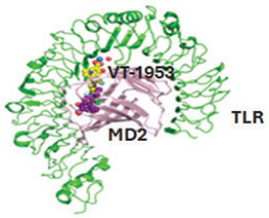
Our solution for treating symptoms of MFW

VT-1953 is being developed as a topical gel treatment for the symptoms of malodorous MFW. It acts via a dual mechanism of action. It can bind and inhibit the DNA gyrase/topoisomerase IV to kill the odor-causing bacteria. Additionally, molecular docking studies show besifloxacin binds at the interface of TLR-MD2 interactions. MD2 is reported to modulate the NLRP3 inflammasome pathway, and can impact multiple mechanisms to reduce inflammation (See **Figure.4**).

Figure. 4. VT-1953 acts via dual mechanisms of action.



The active drug in VT-1953 topical gel binds to DNA gyrase/topoisomerase IV, which kills the odor-causing bacteria colonizing MFWs



It also binds at the interface of MD2-TLR immunomodulatory interaction, which can exert an anti-inflammatory effect in MFW.

The active agent in VT-1953 topical gel is besifloxacin, a fourth-generation fluoroquinolone molecule. A topical ophthalmic drop with the same active ingredient is approved by the FDA (NDA#22-308) for the treatment of bacterial conjunctivitis. Besifloxacin exerts potent efficacy against the range of bacteria commonly colonizing MFW **(See Figure 5a-b)**. Besifloxacin is more potent than metronidazole (currently used off-label to treat MFW) against anaerobes: *Bacteroids* spp (besifloxacin can kill 50% of the bacteria at concentrations of 0.5 µg/ml (MIC50). In comparison, 4X higher concentration of metronidazole is needed to achieve the same level of activity (MIC50 metronidazole=2 µg/ml). Besifloxacin can kill 50% of *Clostridium* bacteria at concentrations of 0.25 µg/ml (MIC50=0.25 µg/ml). In comparison, 8X higher concentration of metronidazole is needed to achieve the same level of activity (MIC50 metronidazole=2 µg/ml for *Clostridium)*. Besifloxacin also kills aerobic bacteria. It can kill 50% of propionibacterium at a concentration of 0.25 µg/ml. In comparison, 64 fold higher concentration of metronidazole is needed for similar level of efficacy (MIC50>16 µg/ml). Besifloxacin can kill 50% to 90% of *Staphylococcus aureus* and *S. epidermidis* at a concentration range of 0.015-0.5 µg/ml (MIC50s/MIC90s range). In comparison, metronidazole does not act against aerobic bacteria. Besifloxacin also demonstrated potent activity against a broad range of streptococci, *Enterococcus faecalis* and *E. faecium*, including vancomycin-resistant enterococci, *Listeria monocytogenes, Acinetobacter spp*., *Enterobacter aerogenes,* and *Proteus spp,* and was active against fluoroquinolone-resistant isolates. For the fastidious gram-negative species (*Haemophilus influenzae, Moraxella catarrhalis, Neisseria meningitidis*, and *Legionella pneumophila*), besifloxacin demonstrated potent activity with MIC90s of 0.03 µg/ml or less. These results show that the active agent in VT-1953 kills a broader range of bacteria that colonize malignant fungating wounds, and at lower concentrations, as compared with metronidazole, which is currently used off-label.

In preclinical studies, VT-1953 was found to exert a direct anti-inflammatory effect independent of the antibacterial effect, reducing inflammation by over 60%. In contrast, FDA-approved anti- inflammatory agent, dapsone, reduced inflammation by 40% in the same study **(See Figure 5c)**. Besifloxacin significantly inhibited lipopolysaccharide-induced cytokine product in a dose-dependent manner. Indeed, cellular and bacterial debris can trigger an innate IL6 immune response via the TLR pathway. Treatment of human monocytes with heat-killed bacteria resulted in the induction of an IL6 response, which was inhibited by VT-1953 in a concentration-dependent manner **(See Figure 5d)**.

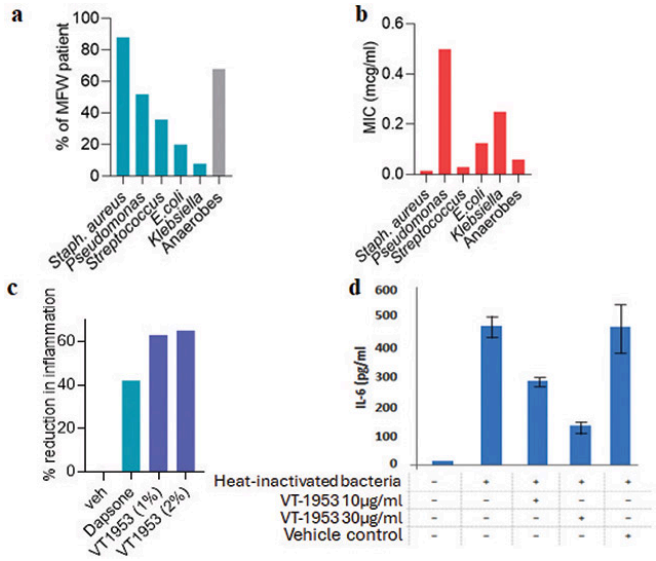
Figure 5.

(a) Graph shows common aerobic and anaerobic bacteria that colonizes MFW.

(b) These aerobic and anaerobic bacteria are killed at low drug concentrations of besifloxacin, the active agent in VT-1953.

(c) Topical application of VT-1953 reduced inflammation, *in vivo*, induced by injection of dead bacteria in rat paw.

(d) VT1953 reduces inflammatory IL6 levels in human monocytes stimulated with heat-killed bacteria. Based on this observation, we anticipate topical application of VT-1953 on MFW will reduce inflammation.



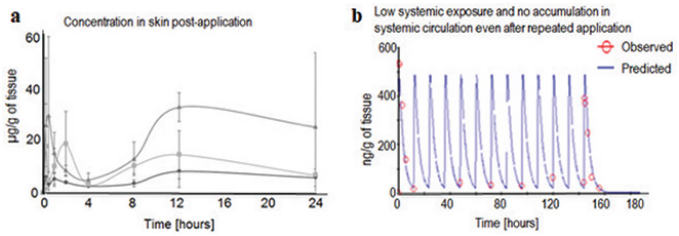
Pre-Clinical Toxicity Studies

Good Laboratory Practice (GLP) and non-GLP repeat dose studies conducted by us, with besifloxacin topical gel application in rodents and minipigs showed very low blood levels but high drug concentration at the site of application on the skin (See **Figure 6**). This is important as local high drug concentration is critical for killing the odor-causing bacteria, while low systemic exposure minimizes the risk of systemic side effects. There were no signs of skin or systemic effects which could be related to treatment with besifloxacin. VB-1953 2% topical formulation was devoid of irritation and allergenic potential in animal models.

Figure 6. VT-1953 topical gel builds desired drug concentration at sit of application on skin with minimal systemic exposure.

(a) Graph shows high drug concentrations (in microgram levels/g tissue) in the skin is retained over 24 hours. This is almost 40x the concentration needed to kill odor-causing bacteria.

(b) In contrast, negligible concentration of drug (in nanograms/g) is reached in systemic circulation, which minimizes the risk of potential systemic side effects.



The toxicokinetics of VT-1953 gel (2% and/or 4%) was evaluated in minipigs following topical application. To model higher systemic exposure, one group was administered the drug via combined topical and subcutaneous administration. In a pilot 7 day non-GLP study, animals were administered VB-1953 gel (4%) twice daily (approx. daily besifloxacin dose of 40mg/kg/day) and a separate group received an additional subcutaneous injection of besifloxacin at 5mg/kg/dose (twice dailyX7 days). Low plasma concentrations were detected following dermal application only at day 7 (and not earlier), with the maximum

plasma concentration (Cmax) being ~2-7 ng/ml and total concentration over time, i.e. the total systemic drug exposure (area under the curve or AUC) being 8-29 ng.h/ml, supporting minimal systemic exposure. Combined subcutaneous and topical application resulted in a rapid Cmax between 425-540 ng.ml between 0.5-1h (Tmax) and AUC values between 1630-2500 ng.h/ml. There were no test article-related effects on clinical signs, dermal irritation, body weight or clinical pathology. These toxicokinetic results mean that while topical application on the skin resulted in minimal systemic exposure, even a 46-154 fold higher exposure on systemic administration was well tolerated.

In a 28 day repeat dose Good Laboratory Practice (GLP) toxicokinetics study required for FDA IND filing, VT-1953 Topical Gel, 0%, 2%, or 4% was applied topically, with resulting daily doses of approximately 0 mg/kg/day, 20 mg/kg/day, and 40 mg/kg/day, respectively (topical dosing alone); a separate group of animals received subcutaneous (SC) injections of 5 mg/kg/dose of besifloxacin twice per day for 28 days followed immediately by dermal application of VT-1953 Topical Gel, 4% to 10% body surface area. A total of 0.4 mg/cm^2 or 0.8 mg/cm^2 of the gel was applied each day. All animals survived to their scheduled termination and there was no test article related effects on clinical signs, dermal irritation, food consumption (qualitative), ophthalmology, electrocardiogram, coagulation, clinical chemistry, and urinalysis parameters. No test article related gross or microscopic pathological findings or organ weight effects were observed. Overall, the relative bioavailability was low via the topical route compared to the subcutaneous route. When comparing the Day 28 AUC values for topical dosing only and combined systemic and topical in the VT-1953 Topical Gel, 4% groups, the values were 18-39 fold lower with topical application than systemic. In this study, a total of 50mg/kg/day was considered the no-observed-adverse effect-level (NOAEL) dose.

In another GLP study, VT-1953 topical gel, 0% (thrice daily), 2% (twice daily), or 4% (twice or thrice daily) was applied topically for 91 days in male and female Gottingen minipigs. All animals survived to their scheduled termination and there was no test article related effects on clinical signs, dermal irritation, food consumption (qualitative), ophthalmology, ECG, coagulation, clinical chemistry, and urinalysis parameters. No test article related gross or microscopic pathological findings or organ weight effects were observed. The topical administration of VT-1953 (4% gel, thrice a day) reaching a dose of 95.7 mg/kg/day was considered as the NOAEL (No Observed Adverse Effect Level) dose. This NOAEL dose converts to a human equivalent dose (HED) of 5220mg for a 60Kg human.

In a GLP study, besifloxacin was administered once daily by oral route in Sprague Dawley rats at the dose levels of 10 mg/kg/day, 30 mg/kg/day, and 100 mg/kg/day for a period of 90 consecutive days. All animals survived to their scheduled termination and there was no test article related effects on clinical signs, food consumption (qualitative), ophthalmology, functional observational battery, motor activity, and coagulation, clinical chemistry, and urinalysis parameters. No test article related gross or microscopic pathological findings or organ weight effects were observed. Based on the study findings, NOAEL dose was considered to be 100 mg/kg/day for besifloxacin when administered repeatedly by oral gavage for 90 consecutive days in Sprague Dawley rats. The human equivalent dose (HED) is 967 mg for a 60Kg human, significantly higher than the 200mg dose per day that we are planning to use as the pivotal dose. We believe that these preclinical toxicity studies are sufficient to support the use of VT-1953 at the 200mg/kg dose that we will use in our clinical studies.

Phase 1 clinical study. Phase 1 clinical trials involve the initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

VT1953 (earlier known as VB-1953) was initially evaluated in a Phase 1 open-label, safety, tolerability and pharmacokinetics study by Vyome in 2017 under the USFDA IND #125,335. The study was conducted in 12 subjects in the US (conducted by Therapeutics Inc. San Diego, CA), sponsored by Vyome Therapeutics Inc), with moderate to severe facial acne vulgaris (Investigator's Global Assessment [IGA] of Grade 3 or 4) as representative of inflamed skin, 18 to 45 years of age, who were treated twice daily for 14 days with VT-1953 topical gel. All subjects applied VB 1953 (2%) gel on the entire face twice daily (every 12 h) from Day 1 morning until Day 15 morning — total number of applications were 29 per subject. The number of subjects (n = 12) in this first-in-man pilot safety, tolerability, and pharmacokinetic study was typical for studies of this type. All subjects were assigned to a single treatment group. No randomization or blinding

was used. All procedures performed in the study were in accordance with the ethical standards of the principles of Good Clinical Practice (GCP) and according to the guidelines (as amended) of the Declaration of Helsinki. The central Institutional Review Board (IRB), Quorum Review IRB, Seattle, USA approval was sought at the site for the initial protocol and for protocol amendments. All participants provided written informed consent before commencing any study-related procedures. Quorum Review IRB approved the informed consent forms (ICF). Study endpoints included:

***(a)* Safety**

- Incidence (severity and causality) of any local and systemic treatment emergent adverse events (TEAEs).
- Number of subjects with presence (and severity) of each individual local skin reaction (LSR: erythema, edema, scaling/dryness, burning/stinging, and pruritus) at each time point collected.
- Changes from Baseline in vital signs at Days 2, 5, 10, and 15.
- Changes from Baseline in electrocardiograms (ECGs) at Days 5, 10, and 15.
- Changes from Screening in clinical laboratory tests (hematology, clinical chemistry, and urinalysis) at Day 15.
- Urine pregnancy test (UPT) results (if applicable) at Baseline and Day 15.

***(b)* Pharmacokinetics**

- Concentration-time profiles of besifloxacin in plasma after the first dose (at Day I) and following the last dose (at Day 15).
- Peak plasma concentration (C_{max}), time to achieve peak plasma concentration (T_{max}), time to achieve minimum plasma concentration (C_{min}), time to achieve minimum plasma concentration (T_{min}), and area under concentration-time curve over a dosing interval (i.e., 12 hours, (AUC,)) after the first dose (at Day 1) and following the last dose (at Day 15), accumulation ratio (AR) after the last dose and terminal exponential half-life ($t_{1/2z}$).
- Trough plasma concentrations (C_{l2h}) on Days I, 2, 5, I 0, and 15 (-12 hours after the last test article application on the previous day).

***(c)* Efficacy (exploratory end points)**

There were no predefined efficacy endpoints. The following acne severity measurements were summarized at Baseline and at Day 15 for descriptive purposes only:

- Investigator's Global Assessment (IGA) score; and
- Inflammatory and non-inflammatory acne lesion counts

The results from this study have been published in a 2020 article titled *"Clinical Pharmacokinetics, Safety and Exploratory Efficacy Study of a Topical Bactericidal VB-1953: Analysis of Single and Multiple Doses in a Phase I Trial in Acne Vulgaris Subjects"* published in the Clinical Drug Investigation, a peer reviewed scientific journal. https://doi.org/10.1007/s40261-019-00883-5.

Of the fifteen subjects assessed, there were three screen failures; one withdrawal by a subject for a personal reason and two who met at least one of the exclusion criteria. The enrolled subjects were both males (33.3%) and females (66.7%) over 18 years of age, with a mean age of 25.3 years (50% whites and 50% Asians).

The safety population included all enrolled subjects who applied at least one dose of VT-1953. Safety data results (vital signs, ECG, physical examinations, hematology, chemistry, urinalysis) were all clinically insignificant from baseline to end of the study (**Figure 7**). UPT results were negative throughout the study. One subject with Treatment -Emergent Adverse Events (TEAE) (vaccination site discomfort) was reported in the study and was not considered related to treatment, was not within the treatment area, did not cause study discontinuation, did not require a change in test article dosing, was non-serious or severe, and resolved within one day after onset. There were no serious adverse events (SAEs). There was a negligible number of

LSRs reported during the study, with all LSRs being trace/minimal or mild in severity. The most common LSR was trace erythema at Day 5 and Day 10. By Day 15, the few LSRs reported had spontaneously resolved with continued administration of the test article, save one subject demonstrating trace amounts of erythema. No edema was reported for any subject during the study. The most common LSR was trace erythema seen at Day 5 and Day 10. However, 11 subjects (91.7%) showed no evidence of erythema by the end of study (EOS). All subjects (100%) showed absence of scaling/dryness, stinging/burning, and pruritus by the EOS. No edema was reported for any subject during the study.

Figure. 7. In a phase 1 study, application of VT-1953 topical gel induced negligible local skin reactions (LSRs), demonstrating the tolerability of using it topically.

LSR parameters	Day 1 (baseline)				Day 2	Day 5	Day 10	Day 15			
	Pre	Post (h)			Pre	Pre	Pre	Pre	Post (h)		
		1	4	12					1	4	12
Erythema											
0-none	12	10	11	11	11	2	6	10	10	11	11
1-trace	0	2	0	1	0	10	6	0	2	1	1
2-mild	0	0	1	0	1	0	0	2	0	0	0
3-moderate	0	0	0	0	0	0	0	0	0	0	0
4-severe	0	0	0	0	0	0	0	0	0	0	0
Scaling/dryness											
0-none	12	7	10	12	11	8	10	11	10	10	12
1-trace	0	4	2	0	0	2	2	0	2	2	0
2-mild	0	1	0	0	1	2	0	1	0	0	0
3-moderate	0	0	0	0	0	0	0	0	0	0	0
4-severe	0	0	0	0	0	0	0	0	0	0	0
Stinging/burning											
0-none	12	11	12	12	11	11	11	12	12	12	12
1-mild	0	1	0	0	1	1	1	0	0	0	0
2-moderate	0	0	0	0	0	0	0	0	0	0	0
3-severe	0	0	0	0	0	0	0	0	0	0	0
Pruritus											
0-none	11	11	10	11	12	10	11	12	12	12	12
1-minimal	1	1	2	1	0	2	1	0	0	0	0
2-moderate	0	0	0	0	0	0	0	0	0	0	0
3-severe	0	0	0	0	0	0	0	0	0	0	0

Number of subjects is 12

Pharmacokinetic parameters were calculated for each subject based on VT-1953 plasma concentrations measured from serial pharmacokinetic blood draws on Day 1 and on Day 15. Following the first topical application of ~ (0.5 — 1.0) g of VT-1953, the quantifiable plasma concentrations of VT-1953 varied between 0.0543 and 0.817 ng/mL until 12 h with mean maximum plasma concentrations of 0.317 ng/mL achieved between 6 to 12 h, a geometric mean peak plasma concentration of approximately 0.264 ng/mL. This supports the preclinical observations, where topical administration resulted in low maximal systemic drug levels. The geometric mean AUCτ, i.e. the total drug exposure, was approximately 1. 921 (ng × h)/mL, supporting minimal systemic exposure over time. *T*max was 8.729 h indicating slow absorption through the skin. Inter-subject variability (CV) associated with these estimates was approximately 72%.

To further understand the pharmacokinetic behavior, trough plasma concentrations of VT-1953 were compared across time (Days 1, 2, 5, 10 and 15) using analysis of variance (ANOVA) with Helmert contrasts. This method compared the concentration over the first collection period versus the mean of all the other trough concentrations. The time at which there was no difference between Day "X" and the mean of all subsequent days was the time to reach steady state. Upon multiple doses, topical application of VT-1953 every 12 h, steady-state was achieved by Day 2 with the trough VT-1953 concentration of 0.13 ng/ml. Difference in VT-1953 plasma concentrations between Day 1 versus subsequent days was highly significant ($p < 0.0001$). When these analyses were expanded to compare differences between all other groups (Day 2 vs > Day 2, Day 5 vs > Day 5 and Day 10 vs Day 15), there was no significant difference ($p > 0.05$) indicating that steady state is achieved by Day 2 of topical application, i.e. there is no systemic drug accumulation. At steady- state, plasma concentrations increased ~ twofold [accumulation ratio (AR) = 1.936; 95% confidence interval (CI) = 1.07 to 3.50]. At Day 15, a *C*max or the highest concentration reached in blood was a geometric mean of 0.46 ng/mL, achieved at a median Tmax of 7.967 h. The minimum concentration detected in blood was a geometric mean (*C*min) of 0.13 ng/mL, while the overall total exposure expressed as a geometric mean (AUCτ) was 3.719 (ng × h)/mL occurring between0h to 12 h. The geometric mean AR was 1.936 (95%

CI 1.07 — 3.50) indicating an approximately twofold increase in plasma concentration of VT-1953 at steady-state when compared to the first application. Inter-subject variability associated with these estimates ranged from 52.75 to 108.4%. The $t_{1/2z}$, i.e. the time for 50% of the drug to be cleared out of the body could only be determined in four subjects, ranging from 6.7 to 17.4 h. These studies support the preclinical observations of minimal systemic exposure with topical application and that steady state is reached within 2 days and there is no drug accumulation in the body when the drug is applied everyday twice daily.

The absolute change in inflammatory lesions from baseline to Day 15 was − 15.3 (59.77% reduction in lesions) (p value < 0.0001) and the absolute change in non-inflammatory lesions from baseline to Day 15 is − 4.5 (13.05%) after topical application of VT-1953 (2%) gel, emphasizing the anti-inflammatory mechanism of action of VT-1953.

Phase 2a 'Proof of Concept' study. This was a double-blind, randomized, vehicle-controlled, parallel-group study to evaluate the safety and efficacy of VT-1953 2% topical gel (earlier known as VB-1953) when applied daily for 12 Weeks in 160 subjects with moderate to severe facial acne vulgaris as representative of inflamed skin. The study was not powered to test for significance of efficacy. The study was done in 2017 – 2018 at the Instituto Dermatologico, Santo Domingo, Dominican Republic, Hospital Clinica Bendana, San Pedro Sula, Honduras, and the Instituto Dermatológico Cirugía de Piel, Santo Domingo, Dominican Republic, and was sponsored by Vyome. Symbio, LLC, Port Jefferson, NY, was responsible for study monitoring, electronic case report forms (eCRFs), quality assurance, data management, biostatistical analysis, and preparation of clinical study report. International Dermatology Research (IDR), Miami, FL was responsible for study monitoring. CISYS Life Sciences, Raleigh, NC, managed the electronic data capture (EDC) system. Subjects were randomized in a 4:4:1:1 ratio to treatment with VT-1953 OD, VT-1953 BID, vehicle OD, or vehicle BID, respectively, applied to the entire face for 12 weeks. Following a Screening/ Baseline Visit on Day 1, subjects returned for follow-up visits at Weeks 2 (Day 15±2 days),4 (Day 29 ±3 days), 8 (Day 57 ±3 days), and 12 (Day 85±5 days). This study was performed in compliance with the principles of the Declaration of Helsinki, current Good Clinical Practice (GCP) guidelines.

Eligible subjects were males or non-pregnant females who were 18 to 45 years old (inclusive) with a clinical diagnosis of moderate to severe (Grade 3 or 4) facial acne vulgaris as determined by the Investigator's Global Assessment (IGA), and at least 20 and no more than 40 inflammatory lesions (papules, pustules), at least 25 and no more than 70 non-inflammatory lesions (open and closed comedones), and no more than 2 nodulocystic lesions (nodules/cysts) on the face, including lesions on the nose. Patients treated with VT-1953 2% topical gel applied twice daily (BID) received a mean total of 114.55 − 117.8 g of 2% gel, or 73.82 − 84.5 g of 2% gel if applied once daily (QD) over the 12 weeks period.

Overall, in the safety population, 31.9% of subjects were males, mean age was 23.5 years (median was 22.0, range 18 to 40), and the majority of subjects were Black or African-American (64.4%) and the remainder were White (35.6%). The end points of the study were:

(a) *Safety assessments*: Safety was assessed by the investigator's evaluation of local and systemic adverse events (AEs), clinical laboratory tests (at Site 02), urine pregnancy testing, vital signs, 12-lead electrocardiograms (ECGs), and physical examination. The investigator assessed local skin reactions (LSRs) of erythema, edema, and scaling/dryness and the subject assessed LSRs of stinging/burning and pruritus/itching. The number and percent of subjects reporting treatment-emergent adverse events (TEAEs) were tabulated by treatment group with summaries presented by system organ class and preferred term for the safety population. Distributions of severity for LSRs were summarized descriptively by visit and treatment group. Changes in vital signs (blood pressure, temperature, pulse rate, and respiration rate) and ECGs were summarized with descriptive statistics.

(b) *Efficacy assessment*: Efficacy was assessed by the IGA of overall acne severity and acne lesion counts at Visits 2, 3, 4, and 5. The primary efficacy endpoints were the absolute change from baseline in inflammatory and absolute change from baseline in non-inflammatory lesion counts at Week 12. The secondary efficacy endpoint was the proportion of subjects achieving IGA success at Week 12 with success defined as a score of "clear" or "almost clear" (IGA Score of 0 or 1, respectively) AND at least a 2-grade (IGA) improvement from Baseline. The proportion of subjects with IGA

success at Week 12 was analyzed using the Cochran-Mantel-Haenszel test for general association stratified by site. Post Hoc analysis of study data offered 106 evaluable patients across the treatment groups for efficacy analysis.

The study enrolled 160 subjects, of which 160 patients were analyzed for safety as intent-to-treat (ITT) populations (any subject who was randomized and received at least one application of the study medication) and 144 were analyzed as per-protocol (PP) population (any ITT subject who completed the study without any significant protocol deviations). TEAEs were reported by 10.2% of total VT-1953 subjects and 15.6% of total vehicle subjects, including 10.6% in the VT-1953 OD group, 9.7% in the VT-1953 BID group, 18.8% in the vehicle OD group, and 12.5% in the vehicle BID group. The most frequently occurring TEAE in the total VT-1953 group was headache (6.3%), which occurred in a similar proportion of subjects with OD and BID dosing. The most frequently occurring TEAEs in the total vehicle group were headache and dysmenorrhea (each 6.3%). All TEAEs were mild or moderate in severity, and none were considered to be related to study medication. No deaths or treatment emergent serious adverse events (SAEs) were reported. Study medication was not interrupted or withdrawn due to TEAEs for any subject. No differences between the OD and BID regimens were demonstrated concerning the nature, severity, relationship to study medication, or frequency of TEAEs or LSRs. Most subjects had a score of "none" for each of the application site LSRs evaluated (erythema, edema, scaling/dryness, stinging/burning, and pruritus/itching). There were no clinically relevant differences between the VT-1953 and vehicle groups for laboratory tests, vital signs, or ECG results. The investigators concluded that the study did not demonstrate any safety concerns with the use of VT-1953 OD or BID.

Treatment resulted in higher reductions from baseline in inflammatory and non-inflammatory lesion counts at Week 12 than pooled vehicles group. The primary endpoint results were similar with VT-1953 OD and BID and were numerically better than with vehicle OD and BID, respectively. PostHoc statistical analysis of study data offered 106 evaluable patients across the treatment groups. Mean percent changes (reduction) in inflammatory lesion counts were 63.7% with VT-1953 QD and 71.5% with VT-1953 BID vs pooled vehicle (P=0.05). IGA success rate at week 12 were also numerically superior in both treatment groups than in pooled vehicles group. The secondary efficacy endpoints were evaluated by percentage of population achieved IGA success rate at week 12. With IGA success defined as a score of "clear" or "almost clear" in both inflammatory and non-inflammatory lesions (IGA Score of 0 or 1) and at least a 2-grade (IGA) improvement from baseline, the success rate at Week 12 was 15.6% with VT-1953 QD, 17.5% with VT-1953 BID, and 9.5% with pooled vehicle.

Phase 2 clinical study: The safety and efficacy of VT-1953 2% Topical Gel, applied once (QD) or twice daily (BID), was tested in a phase 2, randomized, multicenter, double-blind, vehicle-controlled, dose-ranging study. Subjects with moderate to severe inflammatory facial acne vulgaris (representative of inflamed skin). The study was sponsored by Vyome and carried out at 13 sites across the United States. A total of 471 subjects were enrolled in the study, and randomly assigned to treatment; 157 subjects were assigned to VB-1953 QD arm, 79 subjects to the Vehicle QD arm, 156 subjects to the VB-1953 BID arm, and 79 subjects to the Vehicle BID arm. Subjects with a clinical diagnosis of moderate to severe (Grade 3 or 4) facial acne vulgaris, as determined by the Investigator's Global Assessment (IGA), were considered eligible to participate in the study. Subjects applied the assigned Test product to the entire face, either QD or BID, based on the randomization schedule, for 12 Weeks. A total of 428 (90.9%) subjects completed the study; while 43 (9.1%) subjects discontinued. The proportion of subjects who were discontinued from the study was comparable across all treatment arms (VB-1953 QD (10.8%), Vehicle QD (8.9%), VB-1953 BID (7.1%), and Vehicle BID (10.1%). None of the subjects were discontinued from the study due to AEs.

Safety assessments included monitoring of local and systemic adverse events (AEs), local skin reactions (LSRs), physical examinations, vital signs, clinical chemistry and hematology laboratory tests, urinalysis, electrocardiogram (ECG), and urine pregnancy tests (UPTs).

Primary efficacy endpoint was the absolute change from Baseline in inflammatory lesion counts in each treatment arm at Week 12.

There were no deaths or study drug discontinuations due to Treatment-Emergent Adverse Events (TEAEs) during the study. Severe adverse events (SAEs) of severe appendicitis and mild skin laceration were reported in the VB-1953 BID arm and Vehicle BID arm, respectively. Both SAEs were considered not

related to the study drug. Overall, 62 (13.2%) subjects experienced 97 TEAEs. The proportion of subjects experiencing TEAEs following application of the study drug was comparable across all treatment arms. Overall, five TEAEs were considered related to the study drug; supraventricular extrasystoles, eyelid exfoliation, and nasal congestion in the VB-1953 BID arm, alanine aminotransferase increased in the VB-1953 QD arm, and hypocalcemia in the Vehicle BID arm. Overall, the mean and mean changes from Baseline to Week 12 in clinical chemistry, hematology, and urinalysis parameters showed no clinically relevant changes; Three subjects were reported with clinically relevant laboratory values that were recorded as TEAEs; one subject in the VB-1953 QD arm was noted with TEAEs of mild alanine aminotransferase increased (clinically significant (CS), mild blood lactate dehydrogenase increased (not clinically significant (NCS), and mild blood potassium increased (NCS); and a subject in the Vehicle BID arm was noted with a TEAE of mild hypocalcemia (CS); and another subject in the VB-1953 QD arm was noted with a TEAE of mild proteinuria (NCS); The majority of the subjects were recorded with normal urinalysis results at Week 12. However, a few subjects were recorded with shift in the urinalysis results from 'Normal' at Baseline to 'High Normal' at Week 12. One such shift was in the urine protein level in a subject in the VB-1953 QD arm that was recorded as a NCS TEAE of mild proteinuria; Overall, the mean and mean changes from Baseline to Week 12 in vital sign parameters showed no clinically relevant changes. One subject in the VB-1953 BID arm had an abnormal vital sign measurement which was recorded as an abnormal CS TEAE of mild hypertension at Week 4; No abnormal CS physical examination findings were recorded during the study. There were no severe local skin reactions (LSRs) recorded during the study; The LSRs were recorded to be absent (score = 0) for the majority of subjects at Week 12. The mean change from Baseline to Week 12 for all LSRs remained similar across all treatment arms.

At Week 12, in the ITT population, there was a significantly (rank ANCOVA p=0.012 and p=0.047) greater reduction of inflammatory lesion counts in subjects treated with VB-1953 QD and VB-1953 BID compared to subjects treated with pooled Vehicle. Per protocol analysis corroborated the ITT results. At Week 12, in the PP population, there was a significantly (rank ANCOVA p=0.020 and p=0.031) greater reduction of inflammatory lesion counts in subjects treated with VB-1953 QD and BID compared to subjects treated with Pooled Vehicle. At Week 12, the median percent change from Baseline in inflammatory lesion counts in subjects treated with VB-1953 QD and BID was -73.91% (rank ANCOVA p=0.020 vs vehicle- treatment) and -73.44% respectively, suggesting once daily application was as good as bi-daily application.

The majority of the subjects showed an improvement in the Children's Dermatology Life Quality Index (CDLQI) scores from Baseline to Week 12 across all treatment arms with superiority in active treatment arms in comparison with pooled vehicle. In the ITT population, the proportion of subjects who reported a CDLQI score of 0-1 (i.e., facial acne had no effect at all on subject's quality of life) was comparable between the VB-1953 QD (70.4%) and BID (67.8%) arms, and higher than the Pooled Vehicle arm (55.8%) at Week 12 showing numerical superiority of treatment over vehicle. Similarly, the proportion of subjects who reported a dermatology quality of life index (DLQI) score of 0-1 (i.e., facial acne had no effect at all on subject's life) was higher in the VB-1953 BID arm (67.0%) and VB-1953 QD (58.3%) in comparison with Pooled Vehicle (56.5%) arms at Week 12.

In conclusion, the clinical investigators noted the following in their report

(1) The primary efficacy endpoint was achieved as statistically significant greater reductions in inflammatory lesion counts from Baseline to Week 12 were observed for both active treatment arms versus the Pooled Vehicle in the ITT population.

(2) The proportion of subjects experiencing TEAEs following application of the study drug was comparable between VB-1953 treatment arms and Vehicle arms. There were no deaths or study drug discontinuations due to TEAEs during the study. Two SAEs were reported during the study; severe appendicitis in the VB-1953 BID arm and mild skin laceration in the Vehicle BID arm. Both SAEs were considered not related to study drug. Overall, the safety profile of topical VB-1953 gel and Vehicle were comparable when applied either QD or BID for 12 weeks.

(3) The results of this dose-ranging study support advancing the VB-1953 QD dose for further investigation in Phase 3 studies after considering the efficacy and safety profile.

The safety and pharmacokinetics data from the above Phase 1 and 2 clinical studies will be included in future NDA applications to the FDA and other regulatory agencies to support the topical use of VT-1953 to treat different inflammatory conditions, including MFW and inflammatory acne.

Investigator-initiated proof of concept phase 2 clinical study of VT-1953 in Malignant Fungating Wound (MFW). An investigator-initiated POC Ph 2 study to evaluate the safety and efficacy of VT-1953 2% topical gel (labeled as VB-1953A for this study) in advanced cancer patients with malodorous malignant fungating wounds was initiated by Dr. P. Lad, MD, at the Om Sai Onco Surgical Hospital, India in 2024. In investigator- initiated trials (IITs), while the investigator is the sponsor of the trial, the test-agent is provided by Vyome, and we have the rights to reference the data. Male or female subjects aged ≥9 years old, with a diagnosis of malodorous malignant fungating wound malodor corresponding to 0,1 and 2 on the TELER odor scale (where 0= Malodor detected upon entering room (>3m or >10ft) with dressing on; 1= Malodor detected at >2m<3m (between 6-10ft) distance from patient with dressing on; and 2= Malodor detected at ~1m or arm's length to the patient with dressing on, as judged by the investigators) and with an Eastern Cooperative Oncology Group (ECOG) performance status of ≤3 and an anticipated survival of ≥3 months are included in this study. Subjects currently being treated with any antibiotic for bacterial infections or suffering from any infection that may require systemic antibiotic were excluded from the study. The wounds are cleansed with sterile normal saline before treatment. No forceful irrigation techniques and no other cleansing agents were utilized. A total of 7.5g gel was spread evenly across the wound per application. The gel was applied twice daily (B.I.D). The same dressing technique was used throughout the study, consisting of a nonadherent primary dressing, and an absorbent (gauze or nonwoven) secondary dressing.

A total of 10 patients will be enrolled for this study. To put this number in context, in an article "Quantum of Effectiveness Evidence in FDA's Approval of Orphan Drugs" it was noted that Carbaglu (carglumic acid) was approved based on a case series derived from fewer than 20 patients, VPRIV (velaglucerase) was approved based on a pivotal study of 25 patients, Myozyme (alglucosidase alfa) was approved based on a pivotal study that included 18 patients, and Ceprotin (human plasma derived protein C concentrate) was approved based on a study of 18 patients data.

The *primary efficacy endpoint* in this clinical study is the mean score of malodor associated with malignant fungating wounds (scored by investigators) using a 6 point TELER Scale on Day 14. Deodorization of the smell associated with malodorous fungating tumors was used as an endpoint for approval of metronidazole for MFW in the UK. Similarly, in a Ph 3 study for approval in Japan, the percentage of patients who moved to no or non-offensive smell from a mild, moderate or severely offensive smell was used as the primary end point for approval of metronidazole, suggesting that we have a viable path to a regulatory approval. According to the December 2018 guidance on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics Guidance for Industry from the FDA, demonstration of efficacy on a symptom can be a basis for approval in oncology indications.

Other *exploratory endpoints* include the (a) Mean score malodor associated with malignant fungating wounds (scored by investigators) using a 10-point VAS Scale at Day 7 and 14, (b). Mean Pain score associated with the wound as scored by the patient using a 10-point Visual Analog Scale on Day 7 and 14; (c) Mean score of exudates as scored by the caregiver measured on 0-4 scale on Day 7 and 14, and (d) Mean Quality of Life (QOL) score at Day 7 and Day 14 as scored by the patient.

Safety outcome measures include Treatment-Emergent Adverse Events (TEAEs), changes in vital signs, and severity of local skin reactions (stinging/burning, edema).

As of cut off-date, interim analysis of six treated patients shows a statistically significant reduction of malodor at Day 14 from baseline ($p<0.01$) using the TELER scale, the primary end point, when treated with VT-1953 (Figure 8). 100% of the patients exhibited a reduction from moderate to severe odor to mild odor that was detectable only up close after removal of bandage. Similarly, using the 10-point visual analog scale to quantify the change in malodor scored by the patient revealed a statistically significant ($P<0.001$ from baseline) reduction of malodor by Day 14. As shown in Figure 9, treatment with VT1953 resulted in a 75% reduction in malodor from baseline by Day 14 as scored by the patients. Pain scored by the patient using a 10-point visual analog scale similarly showed a statistically significant change ($P<0.05$) on Day 14 from baseline (a reduction of 50%) following treatment with VT-1953 (Figure 9). Treatment with VT-1953 did not significantly change the mean exudate score over the treatment period.

The change from baseline in Quality of Life (QOL) over the treatment period was quantified as an exploratory endpoint. Patients were asked to score on (1) social interactions, i.e. how difficult the patient finds to participate in basic social activities, i.e. interactions with family members; (2) function, i.e. difficulty

in movement due to the wound; and (3) emotional, i.e. how much the patient feels embarrassed in the past week due to the wound odor (i.e. level of self-esteem). The patients were asked to score for each question on a 10 point visual analog scale (VAS). The VAS scores are shown in Figure 10. Treatment with VT-1953 resulted in a 57% improvement in social interactions, 64% improvement in function and 50% improvement in emotional state over the 14 day period. No TEAEs, changes in vital signs, and severity of local skin reactions (stinging/burning, edema) have been noted during the treatment period that can be attributed to the drug.

Figure. 8. VT-1953 topical gel reduced malodor symptom in MFW patients.

Investigators scored malodor on a 6 point TELER scale, where 0 meant severe malodor that could be detected >10ft away with dressings on, while 5 meant no odor detected. The first graph shows the mean TELER score on Day 1 (at start of treatment) and of Days 7 and 14 (primary end point). The right most graph shows the % of patients who showed a 2 point improvement on Day 15 and the % of patients who moved to the mild odor category by end of treatment.

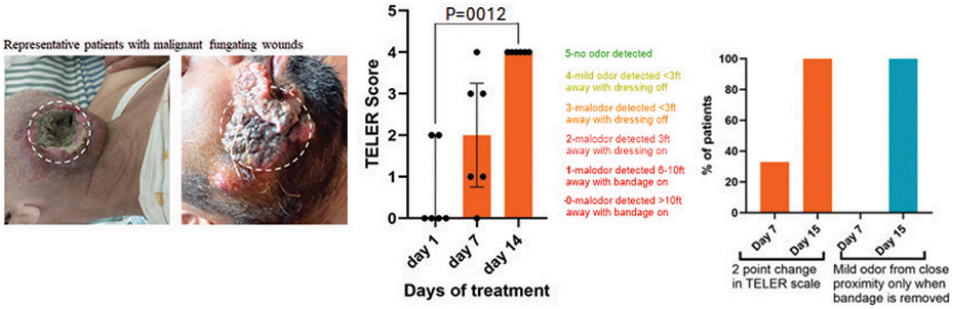


Figure 9. Treatment with VT-1953 topical gel show reduction in MFW symptoms.

Patients scored malodor on a 10 point visual analog scale (VAS). Patients also scored pain at wound site using a 10 point visual analog scale. A significant reduction in both odor (as early as Day 5, p=0.02) and pain (by Day 12, p=0.03) was achieved with VT-1953 treatment.

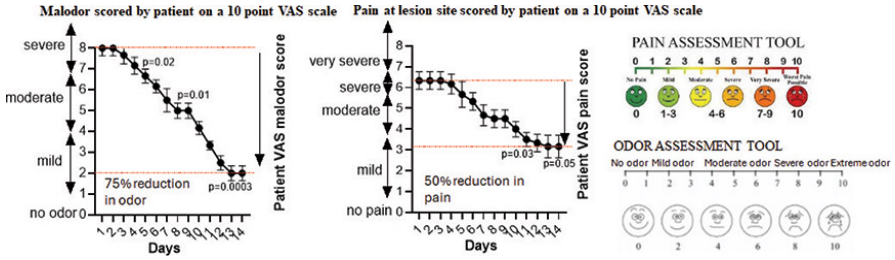
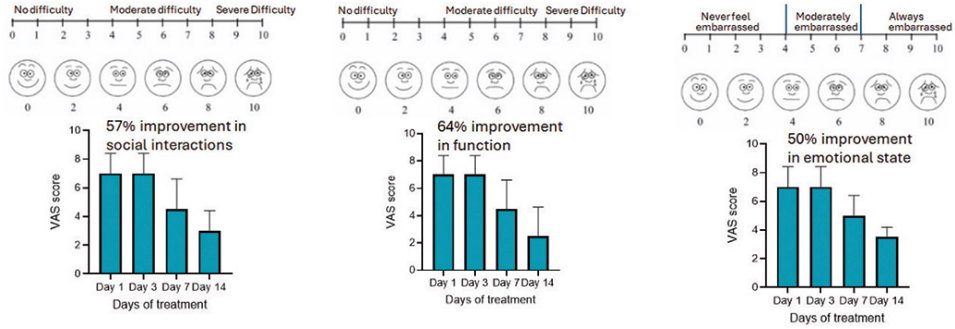


Figure 10. Treatment with VT-1953 topical gel improves quality of life in patients with MFW symptoms.

Social: how difficult the patient finds it to participate in basic social activities (interaction with family members).

Function: difficulties in movement due to the wound using the VAS scale below

Emotional: patient has been embarrassed in the past week due to the wound/odor. Please ask the patient to score between 1 – 10 current level of self-esteem specifically in context to MFW



In summary, we believe VT-1953 has the potential to treat the symptoms of MFW because:

- It kills both aerobic and anaerobic bacteria that cause the malodor and associated symptoms of MFW. It can kill bacteria at lower doses than metronidazole, which is currently used off-label to reduce odor. Indeed, in the Investigator initiated Phase 2 study, the treatment with VT-1953 has resulted in a significant reduction in malodor, the primary end-point, as well as pain at site of lesion (exploratory end point).
- The immunomodulatory mechanism of action of VT-1953 can contribute to reducing inflammation-associated symptoms. Multiple clinical trials have demonstrated the reduction of inflammation following VT-1953 topical gel application.
- Topical application means high drug concentration is reached locally with minimal systemic exposure, which can increase efficacy and reduce the risks of any systemic side effects. In the clinical trial reports, VT-1953 was reported to be well tolerated by patients.

Based on the above observations, we aim to initiate a pivotal study to test the efficacy of VT-1953 in alleviating the symptoms associated with malodorous MFW in early 2025. To date, we have not had any meetings with the FDA regarding Phase 3 trial protocols or regarding obtaining orphan drug designation, and although we plan to receive orphan drug designation, there is no guarantee that such designation will be granted.

Market opportunity for VT-1953

MFW afflicts 5 – 14% of advanced cancer patients in the United States, according to the "The Microbiome, Malignant Fungating Wounds, and Palliative Care" article by Frontiers. Although, from a regulatory perspective MFW is a rare indication, researchers at the National Cancer Institute estimated that over 693,000 Americans will have several forms of advanced cancer by the year 2025. This means between 34,000 to 97,000 patients will suffer from MFW in the US alone without any approved drugs. Globally, an estimated ten million patients have advanced cancer, annually, translating to over 500,000 to 1.4 million patients with MFW. Oncology indications, including treatment of cancer symptoms command premium prices. For example, the average monthly cost to manage cancer pain symptoms for the same drugs is five times that of managing a similar condition in musculoskeletal or neurology indications.

There are currently no drugs that are approved in the US to treat the symptoms of malignant fungating wound. We anticipate that if VT-1953 is approved we can capture a significant portion of the market. Under the Orphan Drug Act, there is a possibility to get seven years of exclusivity for this indication. Additionally, any future competitor will need to demonstrate either superiority or non-inferiority to VT-1953 for approval. Such trials require a larger study population, which is a significant barrier to entry in a rare indication.

Program 2-VT-1908 — Topical drops for treating steroid-incompatible uveitis

Uveitis refers to the inflammation of the uveal tract of the eye (iris, ciliary body and choroid). In the Unites States, the estimated prevalence of non-infectious uveitis is 121/100,000 according to a September 2021

article published in Frontiers in Medicine (Ophthalmology) journal titled "*Epidemiology and Risk Factors in Non-infectious Uveitis: A Systematic Review*." In the developed world, it is the 5th or 6th leading cause of blindness, accounting for about 10 – 15% of all cases of blindness according to a 2004 article in the British Journal of Medicine titled "*Degree, duration, and causes of visual loss in uveitis*" and a 2019 article in the journal Semin Arthritis Rheum titled "*New observations and emerging ideas in diagnosis and management of non-infectious uveitis: A review*." Uveitis can occur due to an infection (infectious uveitis), or if the immune system starts attacking normal cells of the uvea (non-infectious uveitis). Etiologies of non-infectious uveitis include HLA-B27 associated anterior uveitis, Fuchs uveitis syndrome, sarcoidosis, Vogt-Koyanagi-Harada (VKH), sympathetic ophthalmia, birdshot chorioretinopathy, multifocal choroiditis, serpiginous choroiditis, and Behçet disease. Non-infectious uveitis represents the majority of uveitis cases (67 – 90%) in the developed world, according to a 2004 article in the Ophthalmology journal titled "*Incidence and prevalence of uveitis in Northern California; the Northern California Epidemiology of Uveitis Study*" and a 2016 article in the JAMA Ophthalmol titled "*Prevalence of Non-infectious Uveitis in the United States: A Claims-Based Analysis*."

Current treatments for Uveitis

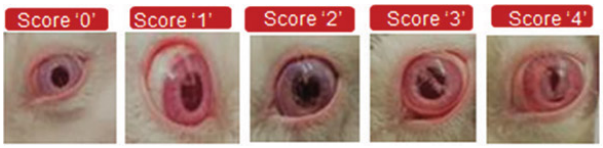
Topical steroids are the first line of treatment for non-infectious uveitis. Steroids deplete the immune cells attacking the uvea. However, long-term use of steroids, such as in chronic and recurrent uveitis, can lead to complications, including glaucoma and cataract. Additionally, uveitic glaucoma is a common complication of uveitis affecting some 20% of patients (more commonly associated with anterior uveitis and with chronic forms of uveitis). Such patients cannot be treated with steroids. Off-label oral or systemic immunosuppressants such as methotrexate or mycophenolate are therefore used as second-line treatments. However, systemically administered immunosuppressants have a lot of side-effects and can deplete the immune system globally and increase the risks of infections. Humira is approved for use in intermediate, posterior, and panuveitis. There is an unmet need for a topically administered non-steroidal drug that can be used to treat uveitis.

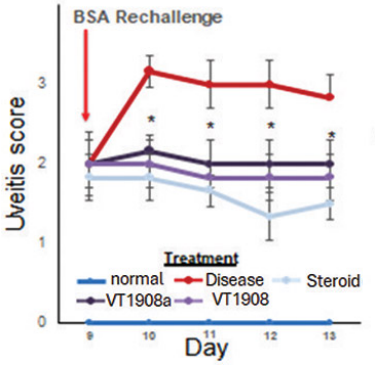
Our solution for treating uveitis. VT-1908 is the first sterile topical eye drop formulation of mycophenolate (salt or ester of mycophenolic acid, MPA), an inhibitor of inosine monophosphate dehydrogenase (IMPDH) enzyme. MPA is a fivefold more potent inhibitor of the type II isoform of IMPDH, which is expressed in activated lymphocytes, than of the type I isoform of IMPDH, which is expressed in most cell types. MPA therefore has e a more potent inhibitory effect on lymphocytes than on other cell types. MPA can induce apoptosis of activated T-lymphocytes, which may eliminate clones of cells responding to antigenic stimulation, decrease the recruitment of lymphocytes and monocytes into sites of inflammation, and suppresses the production by nitrous oxide, and consequent tissue damage mediated by peroxynitrite.

In preclinical studies, treatment with mycophenolate topical eye drops resulted in significant resolution of uveitis comparable to steroid treatment, and reduced the number of infiltrating immune cells in the eye (See Figure11). Mycophenolate is already approved by the FDA as an oral treatment of transplant rejection, and is already used off-label to clinically treat uveitis. For example, in a peer reviewed prospective clinical study published in 2020 the journal Eye, titled "*Mycophenolate sodium (MPS) in the treatment of corticosteroid-refractory non-infectious inflammatory uveitis (MySTRI study)*", the investigators treated forty consecutive patients at a tertiary uveitis referral centre with 6 months of oral MPS with follow-up for 12 months. The main outcome measures were best-corrected visual acuity (BCVA), inflammatory index, steroid-sparing effect of tapering prednisone to ≤10 mg daily and side effects. The investigators concluded that 'MPS is an effective steroid-sparing drug for the treatment of corticosteroid refractory uveitis. The effect seen was not only during the 6 months of therapy, but also extended to 12 months to maintain BCVA and inflammation control. The side effects were acceptable'. The switch to the first sterile topical eye drop offers an opportunity to achieve the drug concentrations at the desired location (eye) and minimize the systemic exposure from oral administration. Based on these observations, we are currently conducting additional pre-clinical studies and manufacturing activities for VT-1908 in anticipation of enabling clinical trials by the end of 2025. The FDA has not approved mycophenolate or mycophenolate sodium to treat patients with uveitis and would need to review clinical trial data in order to determine that these drugs are safe and effective to treat uveitis.

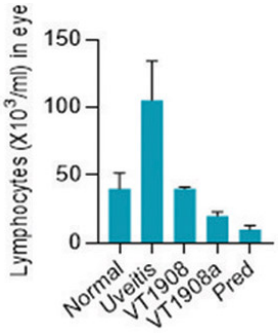
Figure. 11. VT-1908 eye drop is effective against uveitis.

Representative eye images showing the different uveitis scoring levels.





Treatment with different mycophenolate topical eye drops (VT1908, VT1908a) are as effective as a steroid (prednisolone) in treating uveitis.



VT1908 Mycophenolate topical eye drops decreased the infiltrating immune cells in the eye to a similar degree as the steroid (pred) treatment.

Market opportunity for VT-1908

The addressable market potential for replacing topical steroids use in ophthalmology in uveitis is estimated to be $2.6 billion by 2032. In addition, the market potential in other ophthalmology indications, such as in dry eye disease, is estimated to be $13 billion by 2030, in scleritis is estimated to be $4.735 billion by 2030, in blepharitis is estimated to be $2.3 billion by 2031, and in post-operative cataract inflammation is estimated to be $8.78 billion by 2033.

The US has approximately 241,665 anterior non-infections uveitis patients. Taking a mere 12% of the 241,665 patients, we believe we can aim for 30,000 patients to be on treatment with VT-1908 in the US, if it is approved by FDA. With a typical treatment period of six months yearly for anterior uveitis, and an estimated moderate pricing of $1,200 monthly prescription, the annual costs per patient would be approximately $7,200, with a potential yearly sale in the US estimated to be approximately $210 million.

Other pipeline opportunities

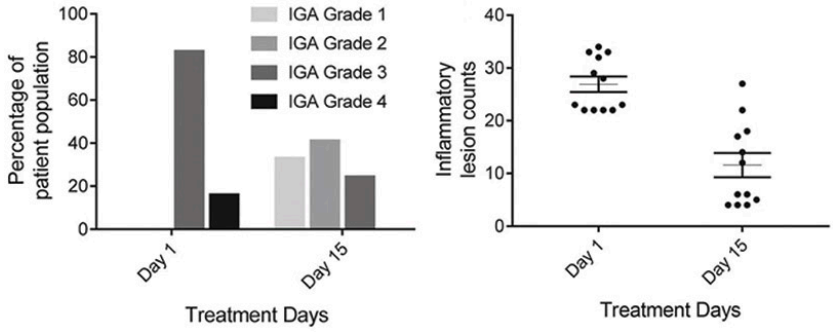
VB-1953 in inflammatory acne — Acne is an inflammatory disease, which according to the American Academy of Dermatology Association afflicts over 50 million Americans annually. It is associated with a bacteria, *P acne*, which can colonize the skin and can lead to inflammation in certain conditions. Acne has been extensively treated with two classes of antibiotics such as clindamycin and tetracyclines (doxycycline, minocycline and sarecycline), and as a result over one in three patients now carry resistant strains, which will not respond to the existing drugs, and as a result, the best response in the reduction of inflammatory lesions with such agents is ~55%. There is a need for novel therapeutics that are active against these resistant strains of *P acne* as well as can independently reduce inflammation for treating inflammatory acne. As VT-1953 meets these two requirements, it can be developed into a potential product for treatment of inflammatory acne.

We have labeled VT-1953 for treatment of inflammatory acne as the VB-1953 program, and both terms can be used interchangeably. As described previously, VT-1953 (VB-1953) 2% gel has been tested in multiple

clinical trials. Below we summarize the results from the studies that have been performed in patients with inflammatory acne (for detailed study description, see the Clinical Phase 1 and 2 studies described earlier).

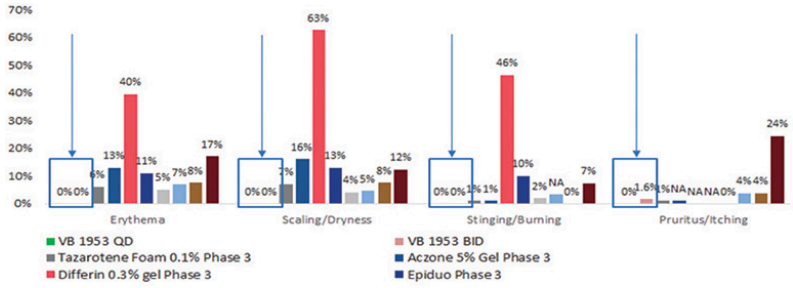
In a Phase 1 open-label study in 12 subjects in the US, with moderate to severe facial acne vulgaris, 18 to 45 years of age, who were treated twice daily for 14 days with VB-1953 Topical Gel, there was a >55% reduction in inflammatory lesions (See Figure12).

Figure 12. Treatment with VB-1953 topical gel reduces inflammatory lesions and improves IGA scores within 15 days in a Phase 1 clinical study in moderate to severe acne patients.



Two Phase 2 clinical studies have been conducted by Vyome on VB-1953 in patients with inflammatory acne. The first was a proof-of-concept 12 week study of 160 subjects conducted in the Dominican Republic which exhibited no safety issues (Fig.14).

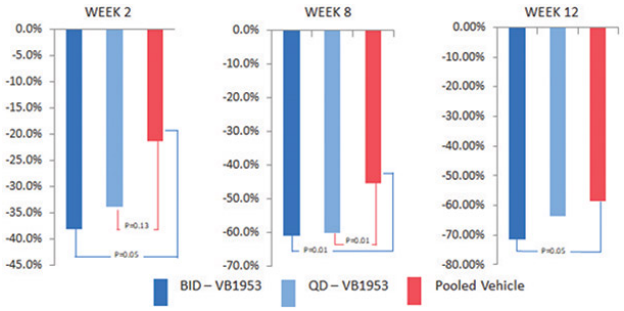
Figure 14. VB-1953 topical gel was well tolerated in a Ph 2 study safety analysis. Percentage of subjects with Local Skin Reaction (LSR)-Moderate and above grade of the LSR at Week 12



* Comparative data was collected from published sources. Trial did not involve direct comparison.

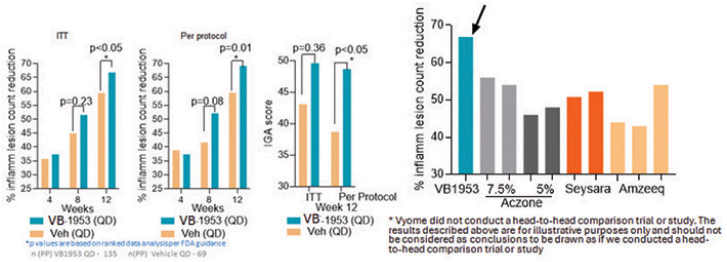
In 106 evaluable patients across the treatment groups, VB-1953 significantly reduced inflammatory lesions with an early onset of action. At two weeks of treatment, VB-1953, applied twice daily (b.i.d) reduced inflammatory lesions by >35% (20% for placebo). At 12 weeks of treatment, VB-1953 (b.i.d) reduced inflammatory lesions by over 70% (See Figure15).

Figure 15. Treatment with VB-1953 topical gel significantly reduces inflammatory lesions in moderate to severe acne patients in a Ph 2 study percent reduction in mean inflammatory Lesion Count



The second Phase 2 dose ranging study was a multi-center, randomized, double-blind, vehicle-controlled, and parallel-arm comparison Phase 2 study in the US in 478 patients with moderate to severe facial acne vulgaris. Subjects treated with VB-1953 had significant reductions (>65%) in inflammatory lesion counts from baseline to week 12. The primary efficacy endpoint was achieved as statistically significant greater reductions in inflammatory lesion counts from Baseline to Week 12 were observed for both active treatment arms versus the Pooled Vehicle in the ITT population. The proportion of subjects experiencing TEAEs and LSRs following application of the study drug was comparable between VB-1953 treatment arms and Vehicle arms (See Figure16). There were no deaths or study drug discontinuations due to TEAEs during the study. Two SAEs were reported during the study; severe appendicitis in the VB-1953 BID arm and mild skin laceration in the Vehicle BID arm. Both SAEs were considered not related to study drug. Overall, the safety profile of topical VB-1953 gel and Vehicle were comparable when applied either QD or BID for 12 weeks. The clinical investigators concluded in their report that the results of this dose-ranging study support advancing the VB-1953 QD dose for further investigation in Phase 3 studies after considering the efficacy and safety profile.

Figure 16. VB-1953 reduced inflammatory lesions in moderate to severe acne patients in a Ph 2 study and safety and tolerability signals were comparable to vehicle-treated controls



Local Tolerability assessment at week 12, Scale 0 (none) to 4 (Severe) in percent (%)												
	VB-1953 QD (N=157)				VB-1953 BID (N=156)				Pooled vehicle (N=158)			
Symptom/ Severity	0 (None)	1 (Trace)	2 (Mild)	3 (Moderate)	0 (None)	1 (Trace)	2 (Mild)	3 (Moderate)	0 (None)	1 (Trace)	2 (Mild)	3 (Moderate)
Erythema	78.5	20.1	1.4	0	75.7	19.6	4.7	0	76.4	18.7	3.5	1.4
Edema	100	0	0	0	96.6	3.4	0	0	97.9	2.1	0	0
Scaling/ Dryness	83.5	13.6	2.9	0	89.9	8.1	2	0	86.8	11.1	1.4	0.7

Investigator-initiated proof of concept phase 2 clinical study of VB-1953 in clindamycin-resistant acne. VB-1953 was studied in an investigator-initiated, open label, single-arm phase 2 clinical study in patients with moderate to severe facial acne vulgaris with poor or no response to previous clindamycin treatment. This study was sponsored by Dr. Rohit Batra, MD (Dermaworld Skin and Hair Clinic, New Delhi)

and Vyome and was completed in 2019. This study has been published as a peer reviewed article in the journal *Drugs in R&D (2020)* for referral.

Healthy male or non-pregnant females aged between 18 and 45 years with a clinical diagnosis of acne vulgaris of moderate to severe grade (grade 3 or 4 as determined by the Investigator's Global Assessment [IGA]) were included in this study. Subjects had at least 20 inflammatory lesions (papules, pustules and nodules/cysts) and at least 20 noninflammatory lesions (open/closed comedones) on the face. Subjects with more than two facial nodulocystic lesions, active nodulocystic acne, and any skin condition or disease interfering with evaluation were excluded. Furthermore, all subjects enrolled in the study had undergone topical clindamycin or clindamycin fixed-dose combination (FDC) treatment in the past month, did not or poorly responded to clindamycin treatment, and harbored clindamycin-resistant *C. acnes* strains. Moreover, subjects with serious clinical illness or chronic diseases, and subjects who had taken certain topical or systemic anti-acne treatments that, in the opinion of the investigator, may interfere with the study, were not included.

This was an open label, non-randomised, prospective clinical study evaluating the safety, tolerability and efficacy of VB-1953 in adult subjects with moderate to severe facial acne vulgaris who did not respond, or had low response, to clindamycin treatment. On Visit 1, an initial screening was performed, followed by collection of a bacterial swab from the patient's face. Thereafter, microbiological testing was performed to check the presence of clindamycin-resistant strains in the samples collected. Of the 80 patients screened, samples from 19 subjects were positive for the above strains, which called for further follow-up visits. On Visit 2, the 19 subjects were enrolled into the study and were assessed for baseline IGA, lesion counts (inflammatory and noninflammatory) and local skin reactions (LSRs). Subjects were instructed to apply VB-1953 (2%) gel on the entire face twice daily for 12 weeks. Visit 2 was then followed by three subsequent visits, i.e. Visits 3, 4 and 5, corresponding to 4, 8 and 12 weeks after Visit 2, respectively. Furthermore, acne swab samples from enrolled patients were collected on Visit 3 (week 4) and Visit 5 (week 12) for microbiology testing. The study was approved by the Independent Ethics Committee (Good Society of Ethical Research [GSER], Delhi, India) and was conducted as per Schedule Y (amended version, 2005) of the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India; 'Ethical Guidelines for Biomedical Research on Human Participants' (2006); Indian Council of Medical Research (ICMR)]; International Conference on Harmonization (ICH) E6-(R1) 'Guideline for Good Clinical Practice'; and Declaration of Helsinki (2013).

All subjects applied VB-1953 topical gel (2%) twice daily (in the morning and evening) for 12 weeks, and were encouraged to report any adverse incidences that happened during the study period. Safety was assessed by evaluation of local and systemic adverse events (AEs) and physical examination. The LSRs of erythema, edema, and scaling/dryness were estimated using a 5-point scale, and the LSRs of stinging/ burning and pruritus/itching were estimated using a 4-point scale.

Efficacy endpoints were acne lesion counts (inflammatory and noninflammatory lesions) and the IGA of overall acne severity (a 5-point static scale). Analysis as per the statistical analysis plan was conducted on the following parameters: (1) absolute change in inflammatory lesions from baseline to week 12; (2) absolute change in noninflammatory lesions from baseline to week 12; (3) proportion of subjects with IGA success. The presence of clindamycin-resistant *C. acnes* in the acne swab samples collected from patients was checked and quantitated by microbiology and molecular biology testings. Additionally, the detection and quantification of drug- resistant C acnes strains were performed in the laboratory using acne swab samples collected from patients.

Eighty subjects were screened for all study inclusion parameters and 19 subjects were finally enrolled in the trial. All subjects completed the trial and were evaluated for safety and efficacy. The enrolled subjects included both males (63.2%) and females (36.8%) in the 18 – 29 years age group, with a mean age of 21.8 years.

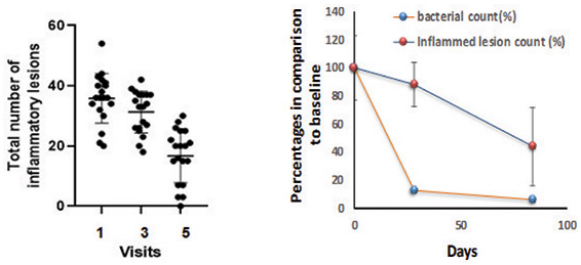
No occurrence of treatment-emergent AEs (TEAEs; local or systemic) or changes in vital signs, physical examinations and urinalysis were reported for any patients during the course of the entire study. A negligible number of LSRs (erythema, edema, scaling, stinging/burning, and pruritus/itching) were reported in the study subjects, with all LSRs being predominantly minimal in severity on all visits, from Visit 2 to Visit 5. One instance of a moderate LSR was observed in a case of stinging/burning and scaling on Visit 2 but was not observed in subsequent visits.

The investigators reported a marked improvement in both inflammatory and noninflammatory lesions after 12 weeks of VB-1953 (2%) topical application, from baseline. The mean inflammatory lesion count decreased from 34.4 ± 6.4 at baseline to 16.7 ± 9.0 at week 12, with a mean reduction from baseline of 53.1% ($p < 0.0001$) (See Figure 13). Similarly, for noninflammatory lesion count, the mean absolute value reduced from 39.4 ± 7.8 at baseline to 19.5 ± 10.0 at week 12, with a mean reduction from baseline of 52.2% ($p < 0.0001$). IGA success at week 12 after topical application of VB-1953 gel (2%) was 26.3%, where IGA success was defined as a score of 'clear' or 'almost clear' (IGA score of 0 or 1) and a grade 2 or higher IGA improvement from baseline. The number of subjects enrolled in the study who had moderate (IGA score of 3) or severe (IGA score of 4) acne at baseline was 18 and 1, respectively. At week 12, five subjects had an IGA score of 1 (almost clear), nine subjects had an IGA score of 2 (mild), and five subjects had an IGA score of 3 (moderate). Overall, 31.6% and 47.1% of subjects exhibited a 2-point and 1-point improvement in IGA score, respectively, while 21.1% of subjects exhibited no change in IGA score compared with baseline at week 12.

C. acnes colonies were isolated from the samples collected from subjects and grown on BHI agar plates. Using the PCR method, the presence of the A2058G mutation on the 23S rRNA gene, and ermX gene detection in DNA extracted from the cells of *C. acnes* colonies, were performed to test for antibiotic-resistant strains. Of the 19 patients with resistant strains, the A2058G mutation in the 50S ribosomal subunit were identified in swab samples of 10 subjects, samples from 7 subjects had *C. acnes* isolates that were ermX gene-positive, and swab samples from two subjects exhibited *C. acnes* strains positive for both the above- mentioned features before start of treatment. At Visit 3 (week 4), acne samples from 10 of 19 subjects enrolled displayed the presence of clindamycin-resistant *C. acnes* strains; this number further decreased to 8 on Visit 5 (week 12) after topical application of VB-1953 gel. Using RT-PCR, we estimated the number of clindamycin-resistant *C. acnes* strains in the acne samples. Figure 13 shows that the resistant *C. acnes* gradually decreased from log 4.9 CFU/mL on Visit 1 to log 3.6 CFU/mL on Visit 5, indicating a decrease in total resistant *C. acnes* by 94.3 ± 1.0% ($p < 0.05$) after 4 weeks of topical application of VB-1953.

The clinical investigator concluded, 'VB-1953 showcased good efficacy in treating both inflammatory and noninflammatory acne lesions without serious adverse effects. While larger studies are necessary to confirm these findings, our present data suggest VB-1953 as a future therapy against acne, even with an underlying resistant C. acnes etiology'.

Figure 13. Treatment with VT-1953 topical gel significantly reduces inflammatory lesions in moderate to severe acne patients carrying clindamycin-resistant bacteria, and non-responsive to clindamycin. Bacterial count shows almost complete eradication of resistant bacteria in the lesions.



Market opportunity for VB-1953

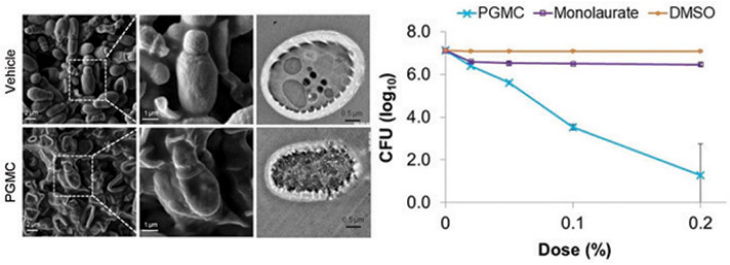
As discussed earlier, our development strategy is to conduct pivotal studies of our drug candidates for rare inflammatory conditions. While VT-1953 demonstrated excellent efficacy in inflammatory acne clinical study, we will conduct pivotal studies in acne only in partnership and will actively pursue such opportunities. We engaged Destum Partners for a market survey in 2019. Based on qualitative interviews with physicians (n = 20) conducted by Destum Partners, dermatologists are unsatisfied with current topical and oral treatment options for inflammatory acne. Destum Partners further conducted payor interviews (n = 5) reflecting coverage over a total of 103 million commercial lives. Based on the product profile of VB-1953 as "A topical treatment for acne patients", demonstrating a 55% (base case) reduction in inflammatory

lesions and an investigator global assessment (IGA) success rate of 25%" (base case), payers would recommend reimbursement of VB 1953, suggesting a Wholesale Acquisition Cost (WAC) price of $300 – 350 per Rx to ensure optimized coverage, projecting a peak US revenue of approximately $400 million according to a report prepared by Destrum Partners, Inc. for the Company in January 2020.

Molecular Replacement Therapeutics ("MRT"):

This is our legacy platform technology (MRT™) for treating fungal diseases that has been licensed by Sun Pharma. We developed an innovative platform, where certain pegylated fatty acids are internalized by disease-causing fungus. These pegylated fatty acids are integrated into the fungal cell membrane, leading to instability of the cell membrane and fungal cell death (See Figure 17). The combination of the MRT platform with conventional antifungal agents was shown to overcome fungal resistance against the conventional agents. Sun Pharma has already commercialized one product with the MRT technology. We anticipate expansion of the partnership to other products.

Figure 17. Treatment with PGMC (MRT) disrupts fungal membrane, resulting in clearance of fungal infection



We have partnered with Sun Pharma for the exclusive marketing in India of our dandruff treatment shampoo and lotion, both based on MRT technology. Additionally, we have licensed our MRT technology-based Luliconazole cream to Sun Pharma for exclusive manufacturing and marketing in India.

Intellectual Property

Overview

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection in the United States and internationally for our current and future product candidates. We also rely on trademarks, copyrights, trade secrets, confidentiality procedures, employee disclosure, invention assignment agreements, know-how, continuing technological innovation and in- licensing opportunities to develop and maintain its proprietary position.

We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to platform technologies and improvements thereof, pharmaceutical compositions, methods of treatment, methods of manufacture or identified from its ongoing development of our product candidates. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce any patents that we may obtain, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

The patent positions of companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings,

which may result in further narrowing or even cancellation of patent claims. We cannot guarantee that our pending patent applications, or any patent applications that we may in the future file or license from third parties, will result in the issuance of patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover our product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage. We cannot predict the scope of claims that may be allowed or enforced in its patents. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. Also, due to cost rationalization of patent related expenses and due to lack of financial resources, certain patent applications or patents may get abandoned from time to time.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patent applications or the first to file patent applications covering such subject matter, and we may have to participate in interference proceedings or derivation proceedings declared by the USPTO to determine priority of invention. For more information regarding the risks related to our intellectual property, see "*Risk Factors — Risks Related to Vyome — Risks Related to Vyome's Intellectual Property*."

Patent Portfolio

We have taken an aggressive approach to file and build a patent portfolio around our technology. We have granted patents and filed patent applications around our VB-1953 product and its use in antibiotic-resistant acne and inflammatory acne conditions. We have also filed patents around VT-1953 for use in treating malodor in MFW and VT-1908 product for use in the treatment of uveitis. We also have patents in the U.S, Japan, India, and South Korea around our MRT technology

- List of Key Granted Patents and Patent applications

Country	Patent Application Number / Granted Patent Number	Current Status	Expiry Period	Type of patent protection
China	Granted Patent Number: 201580016977.5	Granted Patent	January 2034	Formulation and use
China	Patent Application Number: 202110758695.X	Divisional application — Under examination	January 2034	Formulation and use
Eurasia	Patent Application Number:201691534	Application under examination	January 2034	Formulation and use
Europe	Granted Patent Number: EP3099301B1	Granted Patent	January 2034	Formulation and use
Great Britain	Granted Patent Number: EP3099301B1	Granted Patent	January 2034	Formulation and use
France	Granted Patent Number: EP3099301B1	Granted Patent	January 2034	Formulation and use
Germany	Granted Patent Number: EP3099301B1	Granted Patent	January 2034	Formulation and use
Italy	Granted Patent Number: EP3099301B1	Granted Patent	January 2034	Formulation and use
Spain	Granted Patent Number: EP3099301B1	Granted Patent	January 2034	Formulation and use

Country	Patent Application Number / Granted Patent Number	Current Status	Expiry Period	Type of patent protection
Netherland	Granted Patent Number: EP3099301B1	Granted Patent	January 2034	Formulation and use
Honk Kong	Patent Application Number: 42022051670.2	Application under examination	January 2034	Formulation and use
India	Granted Patent Number:539669	Granted Patent	January 2034	Formulation and use
Japan	Granted Patent Number: 6767265	Granted Patent	January 2034	Formulation and use
Mexico	Granted Patent Number: 394441	Granted Patent	January 2034	Formulation and use
New Zealand	Granted Patent Number: 761261	Granted Patent	January 2034	Formulation and use
South Africa	Granted Patent Number: 2016/05946	Granted Patent	January 2034	Formulation and use
USA	Granted Patent Number: US10071103B2	Granted Patent	January 2034	Formulation and use
USA	Granted Patent Number: US11045479B2	Granted Patent	January 2034	Formulation and use
Malaysia	Granted Patent Number: MY-188541-A	Granted Patent	January 2034	Formulation and use

Formulations and Method for Treatment of Inflammatory Diseases VT-1908

Country	Patent Application Number / Granted Patent Number	Current Status	Expiry Period	Type of patent protection
China	Patent Application Number: 202080096982.2	Application under examination	December 2039	Formulation and use
USA	Patent Application Number: 17/787,303	Application under examination	December 2039	Formulation and use

VT-1953 A method of treating Malignant fungating wound using Besifloxacin.

Country	Patent Application Number / Granted Patent Number	Current Status	Expiry Period	Type of patent protection
USA	Patent Application Number: 63/660,067	Provisional application. PCT due by June 2025	June 2044	Formulation and use

MRT Technology based products

Country	Patent Application Number / Granted Patent Number	Current Status	Expiry Period	Type of patent protection
India	Granted Patent Number: 381425	Granted Patent	December 2031	Formulation and use
Japan	Granted Patent Number: JP6339940B2	Granted Patent	December 2031	Formulation and use
South Korea	Granted Patent Number: KR102009698B1	Granted Patent	December 2031	Formulation and use
USA	Granted Patent Number: US10232047B2	Granted Patent	December 2031	Formulation and use

We intend to maintain, deepen, extend and protect our global IP portfolio. We may seek to form strategic alliances, enter into licensing agreement, or collaborate with third parties to strengthen and aid our

research and development and IP portfolio. We are also actively engaged in evaluating additional assets and complementary technologies for in-licensing and may execute additional transactions to add to our pipeline. We believe our leadership has a proven track record for identifying and transacting upon de-risked clinical stage assets.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with its employees, consultants, scientific advisors, contractors, and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of its proprietary information by third parties.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technologies. Thus, we may not be able to meaningfully protect its trade secrets. For more information regarding the risks related to our intellectual property, see "*Risk Factors — Risks Related to Vyome's Business — Risks Related to Intellectual Property*."

Business Development Initiatives

We intend to explore partnerships for licensing or co-developing VB-1953 in the US and other markets worldwide. Additionally, we plan to evaluate and explore in-licensing novel and innovative products that treat immune-inflammatory diseases from companies in the US, India and other countries. as part of our strategic portfolio expansion. We are also continuing to explore opportunities to expand partnerships for our MRT technology products in other countries.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property. While we believe that our differentiated technologies and products, scientific expertise, and intellectual property position provide us with competitive advantages, we face potential competition from a variety of companies in these fields. There are several companies that develop treatments for wounds, uveitis, inflammatory acne, and other immune-inflammatory conditions using different technologies including Tarsier Pharma, Eli Lily, Eyepoint Pharmaceuticals, Bausch Health, Sun Pharma, and Almirall. Several additional companies utilize other technologies to develop competing products.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for our product candidates. This may include other types of therapies, such as small molecule, antibody, and/or protein therapies.

In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, and approved products than we do today. Mergers and acquisitions in the pharmaceutical and biotechnology may result in even more resources being concentrated among a smaller number of its competitors. Many of these companies are publicly listed entities and have access to larger financial resources. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We also compete with these companies in recruiting, hiring, and retaining qualified scientific and

management talent, establishing clinical trial sites and patient registration for clinical trials, obtaining manufacturing slots at contract manufacturing organizations, and in acquiring technologies complementary to, or necessary for, its programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, and more effective, particularly if they represent cures, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our assets, which could result in our competitors establishing a strong market position before we can enter the market. We believe the key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, availability of reimbursement, access to capital, and human resources. As a result, we cannot assure that we will be able to compete effectively against these companies or their products.

Commercialization

We have commercialized three products based on MRT technology in India in partnership with Sun Pharma. In this partnership, we arrange for supplies of our dandruff shampoo and lotion to Sun Pharma for which we earn service fees and royalties. We also have commercialized our MRT technology-based Luliconazole cream in partnership with Sun Pharma in India by licensing the technology earning milestone payments and royalties and profits in arranging the supply of a proprietary ingredient sourced by us.

Under our Supply and Marketing Agreement related to dandruff products, as amended with Sun Pharma, we granted an exclusive right to Sun Pharma to launch, market, promote sell, and distribute the products (Anaboom AD Shampoo 20 mL, Anaboom AD Shampoo 100 mL and Anaboom AD Lotion 50 mL) in India through the marketing channel (as defined under the agreement) for which Sun Pharma agreed to purchase and take delivery of certain minimum guaranteed volumes of products. Under the agreement, Vyome is obligated to have the products manufactured in accordance with agreed-upon specifications and applicable laws, and Sun Pharma granted a license to Vyome to use its brand name in order for Vyome to manufacture and deliver these products to Sun Pharma. Sun Pharma is obligated under the agreement to purchase and take delivery of the minimum guaranteed volumes of the products from Vyome in every sales year as set forth in the agreement.

In consideration for the exclusive rights granted to Sun Pharma, Vyome was entitled to an upfront fee of INR 10,00,000 (approximately $11,849). Vyome is also entitled to receive from Sun Pharma, launch fees as follows: (i) upon launch of each product a sum of INR 3,000,000 (approximately $35,546), (ii) a sum of INR 3,500,000 (approximately $41,470) on the first anniversary of the first invoice. Vyome is also entitled to royalty of 1.25% of the net sales of each product (exclusive of taxes).

Each party has the right to terminate the agreement if the other party commits a material breach such party's obligations under the agreement upon 45 days' written notice to cure such breach and if such breach remains uncured. In addition, Vyome has a right to terminate the agreement if Sun Pharma does not launch the products within the timeframe set forth in the agreement. Sun Pharma also has a right to terminate the agreement in the event Sun Pharma fails to launch any of the products due to Vyome not notifying Sun Pharma of the availability of the finished products mentioned in the first purchase order within 6 months of the fate of the first purchase order or finalization of all the packaging material and vendors, whichever is later.

Under our Development and Licensing Agreement with Sun Pharma, we granted to Sun Pharma rights to our technology to develop Luliconazole based cream and lotion formulation, manufacture, and commercialize such products in India. In consideration thereof, Sun Pharma agreed to pay Vyome certain upfront fees and other milestone payments, including the payment of INR 5,000,000 (approximately $59,311), upon the successful completion of certain studies and INR 10,000,000 upon successful launch or first invoicing of the products by Sun Pharma (approximately $118,623). This milestone has already been achieved. Vyome is also entitled to a royalty of 5% of the net sales of each product (inclusive of taxes). The agreement also provides for a payment of INR 10,000,000, (approximately $118,623) upon a positive or satisfactory of the clinical trial study conducted on the product. However, such a clinical trial study has not been completed yet. In addition, Vyome is entitled to additional sales-linked milestone payments as per the schedule given below:

(1) Should Sun Pharma decide to launch the product after a positive outcome from the clinical trial then Vyome shall be entitled to sales linked milestone payments in the manner set out below:

(a) INR 10,000,000 (approximately $118,623) (upon net sales of all products of INR 250,000,000 (approximately $2,965,575) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(b) INR 15,000,000 (approximately $177,934) (upon net sales of all products of INR 500,000,000 (approximately $5,931,150) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(c) INR 10,000,000 (approximately $118,623) (upon net sales of all products of INR 750,000,000 (approximately $8,896,725) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(d) INR 10,000,000 (approximately $118,623) (for every INR 250,000,000 (approximately $2,956,575) incremental sales of all products together upon net sales of INR 1,000,000,000 (approximately $11,862,300) for any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

If the clinical trial is not completed within time period of sixteen months plus the additional time of delays that are not attributed to Sun Pharma, from the effective date of the Development and Licensing Agreement (December 15, 2020), it would be considered as complete and considered as clinical trial is successful.

(2) Should Sun Pharma decide to launch the product in spite of negative outcome of the clinical trial, then Vyome shall be entitled to sales linked milestone payments in the manner set out below:

(a) INR 5,000,000 (approximately $59,311) (upon net sales of all products of INR 250,000,000 (approximately $2,965,575) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(b) INR 7,500,000 (approximately $88,967) (upon net sales of all products of INR 500,000,000 (approximately $5,931,150) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(c) INR 5,000,000 (approximately $59,311) (upon net sales of all products of INR 750,000,000 (approximately $8,896,725) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(d) INR 50,00,000 (approximately $59,311) (for every INR 250,000,000 (approximately $2,956,575) incremental sales of all products together upon net sales of INR 1,000,000,000 (approximately $11,862,300) for any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

The Development and Licensing Agreement is for an initial term of five years, after which the Agreement may be renewed for an additional five years upon mutual agreement of the parties. Each party has the right to terminate the agreement if the other party commits a material breach of such party's obligations under the agreement upon 90 days' written notice to cure such breach and if such breach remains uncured. In addition, Vyome has a right to terminate the agreement if Sun Pharma does not launch the products within the timeframe set forth in the agreement. In addition, either party may terminate due to breaches of the confidentiality obligation and the Company shall have a right to terminate upon infringement of the intellectual property rights by Sun Pharma after 45-days' notice detailing and providing proof of the breach.

Should any of our other product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the United States and other key markets, through internal infrastructure and/or external partnerships in a manner that will enable us to realize the full commercial value of our programs. Given the company's stage of development, we have not yet established a commercial organization or distribution capabilities in the USA and other key markets.

Our Manufacturers and Suppliers

To date, all of the materials and components for our products, as well as any related outside services, are procured from qualified suppliers and contract manufacturers in accordance with our proprietary specifications. Our key manufacturers and suppliers have experience working with our MRT technology-based products,VT-1953 and VB-1953 are GMP certified and are regularly audited by various regulatory agencies in India and by the FDA. Our key manufacturers and suppliers have a demonstrated record of compliance with regulatory requirements.

Given that we rely on third-party manufacturers and suppliers for the production of our products, our ability to increase production going forward will depend upon the experience, certification levels, and large-scale production capabilities of its suppliers and manufacturers. Qualified suppliers and contract manufacturers have been and will continue to be selected to supply products on a commercial scale according to our proprietary specifications. The FDA approval process may require us to name and obtain approval for the suppliers of underlying products of our assets.

We may not be able to quickly qualify and establish additional or replacement suppliers for the components of its products. Any new approvals of vendors required by the FDA or other regulatory agencies in other international markets for our products as a result of the need to qualify or obtain alternate vendors for any of our components would delay our ability to sell and market its products and could have a material adverse effect on our business.

We believe that our current manufacturing and supply arrangements can be scaled to support commercial sales and our planned clinical trials. To produce our products in the quantities we anticipate meeting future market demand, we will need our manufacturers and suppliers to increase, or scale up, manufacturing production and supply arrangements by a significant factor over the current level of production. There are technical challenges to scaling up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and suppliers and hiring and retaining additional management and technical personnel who have the necessary experience. If our manufacturers or suppliers are unable to do so, we may not be able to meet the requirements to expand the launch of our products in the United States or launch our products internationally, or to meet future demand, if at all. We may also represent only a small portion of our suppliers' or manufacturers' business and if they become capacity-constrained, they may choose to allocate their available resources to other customers that represent a larger portion of their business. If we are unable to obtain a sufficient supply of its product, our revenue, business, and financial prospects will be adversely affected.

Governmental Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, clinical trial, testing, manufacture, quality control, import, export, safety, efficacy, labeling, packaging, storage, distribution, recordkeeping, approval, distribution, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, CROs, clinical investigators, and CMOs will be required to navigate the various preclinical, clinical, manufacturing, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of its product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

Overview of U.S. Drugs Development Process

In the United States, the FDA regulates drug products under the Federal Food, Drug and Cosmetic Act (FD&C Act) and its implementing regulations. Drugs are also subject to other federal, state, and local statutes and regulations. If we fail to be compliant with these regulations, then we may be subject to warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties, or criminal prosecution.

Our product candidates must be approved for therapeutic indications by the FDA before they may be marketed in the United States. For drug product candidates regulated under the FD&C Act, the FDA must approve a New Drug Application or NDA. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- completion of the manufacture, under cGMP conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before clinical trials may begin;
- payment of user fees for FDA review of the NDA;
- approval by an International Review Board or IRB or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, Good Clinical Practice or GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug product's identity, strength, quality and purity;
- satisfactory completion of potential FDA audit of the preclinical study clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA, including, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes the results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a clinical trial may move forward at designated check points based on access that only the group maintains to available data from the trial and may recommend halting the clinical trial if it determines that the participants or patients are being exposed to an unacceptable health risk or other grounds, such as no demonstration of efficacy. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, FDA will nevertheless accept the results of the study in support of an NDA if the study was well-designed and well-conducted in accordance with GCP requirements, including that the clinical trial was performed by a qualified investigator(s); the data are applicable to the U.S. population and U.S. medical practice; and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1* — Phase 1 clinical trials involve the initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- *Phase 2* — Phase 2 clinical trials typically involve the administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. In certain cases, such as in oncology indications, as articulated in a 2012 article on approval of new agents after phase II trials in the American Society for Clinical Oncology Educational Book, *"A confirmatory phase II trial, which need not be randomized if an active control is not available' (as is our case as there are no approved drugs), can provide sufficient evidence to convince regulatory authorities to grant accelerated approval, and the process can be completed in three years or less." Similarly,* Macaulay, R. in the article entitled 'EMA Approval of Drugs on the Basis of Pivotal Non-Comparative Phase II Trial Data. Value in Health, Volume 16, Issue 7, A324' wrote "in conclusion that Pivotal Phase II data can support EMA approval if it demonstrates substantial clinical benefits for small patient populations with severe diseases that lack therapeutic alternatives" (as is the case with MFW). In a recent example, Adaptimmune Therapeutics was reported to be making a submission to the FDA after 42% of patients with sarcoma responded to the company's

investigational therapy in a pivotal phase 2 trial (primary analysis includes 64 patients, and was an open-label study, dubbed IGNYTE-ESO). Hence, it is routine in malignant indications to file for approval and pre-phase 3 studies can serve as pivotal studies for such filings.

- *Phase 3* — Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling. Generally, two adequate and well-controlled Phase 3 trials are required by the FDA for approval of an NDA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of NDA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information. During the development of a new drug product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2 and before submission of an NDA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and efficacy for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug, to the satisfaction of the FDA. FDA must approve an NDA before a drug may be marketed in the United States.

The FDA reviews all submitted NDAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt,

and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the product is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards, including cGMP requirements, designed to assure and preserve the product's continued identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategies or REMS if it believes that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, special monitoring or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential

market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population of 200,000 or more individuals in the United States when there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and user-fee waivers.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan-designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

The FDA may further reevaluate its regulations and policies under the Orphan Drug Act. It is unclear as to how, if at all, the FDA may change the orphan drug regulations and policies in the future.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients more quickly than standard FDA review timelines typically permit.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the FDA may review portions of the marketing application before the sponsor submits the complete application.

In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed

early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient product development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review, once an NDA is submitted, if the product that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review.

Products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated Approval is usually contingent on a sponsor's agreement to conduct, in a diligent manner, adequate and well- controlled additional post-approval confirmatory studies to verify and describe the product's clinical benefit, and under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Further, under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product or an indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for Accelerated Approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

U.S. Post-Approval Requirements for Drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities.

Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Promotional materials for approved drugs must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing

processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post- market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs and those supplying products, ingredients and components of them, are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements on sponsors and their CMOs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that a sponsor may use. Additionally, manufacturers and other parties involved in the drug supply chain for prescription drugs must also comply with product tracking and tracing requirements and for notifying FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with statutory and regulatory requirements may subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program user fee for any marketed product.

The FDA may withdraw approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and issuance of corrective information.

Privacy and Cybersecurity

Our operations entail the collection, use, disclosure, transfer, and processing of sensitive and personal information. These operations now and in the future are subject to multiple jurisdictions' privacy and data security laws and regulations, including those within the U.S., the EEA, and the UK. Our operations extend to commercial partnerships and third-party processors, each of which may be governed by their distinct privacy regulations and data security laws. These laws are constantly evolving and subject to varying interpretations, requiring us to periodically update its policies and measures to maintain compliance.

The GDPR in the EU and the UK, which have been incorporated into their respective laws, impose stringent requirements on the processing of health and other sensitive data. These requirements encompass: (i) providing information to individuals regarding data processing activities; (ii) obtaining consent from individuals to whom the data processing relates; (iii) responding to data subject requests; (iv) imposing requirements to notify the competent national data protection authorities and data subjects of personal data breaches; (v) implementing safeguards in connection with the security and confidentiality of the personal data; (vi) accountability requirements; and (vii) taking certain measures when engaging third-party processors. The GDPR is also the regulation that informs us obligations with respect to any clinical trials conducted in the EEA or UK. The GDPR's definition of personal data includes coded data, and it requires changes to informed consent practices and detailed notices for clinical trial subjects and investigators. Failure to comply with the GDPR can result in significant practical, legal, and financial repercussions, including the destruction of improperly gathered or used personal data, substantial fines of up to €20 million (£17.5 million) or 4% of the company's global annual turnover, mandatory audits, orders to cease or modify data use, and a private right of action enabling data subjects to seek damages. In addition, the GDPR provides that EU member states or the UK may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric, or health data.

Further, the UK has recently introduced a new Data Protection & Digital Information (No. 2) Bill. This development could reshape the UK's data protection landscape, distancing it from the EU's data protection regime. This lack of clarity on future UK laws and regulations and their interaction with those of the EU could add legal risk, uncertainty, complexity, and cost; and any resulting divergence in laws could increase our risk profile and necessitate further compliance measures.

To enable the transfer of personal data outside of the EU or the UK, adequate safeguards must be implemented in compliance with the GDPR. On June 4, 2021, the European Commission issued new forms of standard contractual clauses, or SCCs, for data transfers from controllers or processors in the EU (or otherwise subject to the GDPR) to controllers or processors established outside the EU (and not subject to the GDPR). As of December 27, 2022 the new SCCs replace the SCCs that were adopted previously under the EU Data Protection Directive. The UK is not subject to the European Commission's new SCCs, and instead it has published the UK International Data Transfer Agreement, or IDTA, and the International Data Transfer Addendum to the new SCCs, or the Addendum, which enable transfers from the UK. For new transfers, the IDTA (or SCCs and Addendum) must be in place, and such measures must be in place for all existing transfers from the UK from March 21, 2024. Companies relying on SCCs or the IDTA to govern transfers of personal data to third countries will also need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR, including an analysis of the laws in the recipient's country. When conducting restricted data transfers under the EU and UK GDPR, we will need to implement these new safeguards, and doing so will require significant effort and cost.

Failure to implement valid mechanisms for personal data transfers from Europe may result in increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to export personal data may also: (i) restrict our activities outside Europe; (ii) limit the ability to collaborate with partners as well as other service providers, contractors and other companies outside of Europe; and/or (iii) require us to increase its processing capabilities within Europe at significant expense or otherwise cause it to change the geographical location or segregation of its relevant systems and operations — any or all of which could adversely affect its operations or financial results.

In the U.S., privacy and security of personal information are regulated by various federal and state laws, such as health information privacy laws, security breach notification laws, and consumer protection laws.

Compliance with these multifaceted privacy and data security laws can be time-consuming, and failure to comply with any of these regulations could lead to significant fines and penalties (potentially including criminal prosecution), adversely affecting our reputation, business, financial condition, and operational results. Changes in statutes, regulations, or interpretations of existing regulations could impose additional requirements on our operations, such as modifications to data processing arrangements, changes to privacy policies, recall or discontinuation of certain data processing methods, or additional recordkeeping requirements. These changes could adversely affect the operation of our business.

There is a further risk that we may not be able to adequately protect its information systems from cyberattacks. Such breaches could result in the disclosure of confidential, protected, or personal information, damage its reputation, and expose it to significant financial and legal exposure, including potential civil fines and penalties, litigation, and regulatory investigations or enforcement actions under laws such as HIPAA, the GDPR, and the CCPA.

In addition to the risks outlined above, the legal or regulatory actions may also divert our management from their primary operations. Prohibitions, restrictions, or allegations of violations of these laws could materially and adversely affect our business. Hence, ensuring consistent compliance with privacy and data security laws and regulations remains a critical operational imperative for us.

Other Regulatory Matters

Manufacturing, labeling, packaging, distribution, sales, promotion, and other activities of product candidates following product approval, where applicable, or commercialization are also potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject. Additionally, the activities associated with the commercialization of product candidates are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the CMS, other divisions of the U.S. Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage and security requirements intended to prevent the unauthorized sale of such pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert its management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in statutes, regulations, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Regulation Outside of the United States

In addition to regulations in the United States, we subject to a variety of regulations in other jurisdictions governing clinical studies, commercial sales, and distribution of our products. Most countries outside of the United States require that clinical trial applications be submitted to and approved by the local regulatory authority for each clinical study. In the EU, for example, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Under the new CTR (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System, or CTIS, for clinical trial authorization in up to 30 EU/ EEA countries at the same time and with a single set of documentation. A similar process is followed in other countries like India, China and Japan etc.

Insurance Coverage

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement

from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize its product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

Additionally, the process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

No Uniform Policy Exists for Coverage and Reimbursement in the U.S.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Further, during the COVID-19 pandemic, millions of individuals lost employer-based insurance coverage. It is unclear what effect, if any, the American Rescue Plan will have on the number of covered individuals, which may adversely affect our ability to commercialize its products. A similar situation may happen due to any other pandemic in future.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

Affordable Care Act and Legislative Reform Measures

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell its products profitably. In particular, in 2010, the ACA was enacted, which, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug

Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, and executive, challenges to certain aspects of the ACA. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, the Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our B business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs without generic competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. Further, judicial challenges to the IRA may have an impact on the implementation of the IRA's provisions; and the overall effects of the IRA on Bio's business and the healthcare industry in general is not yet known.

These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Other U.S. and India Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance for employees in India to cover costs and expenses we may incur due to injuries to its employees as well as insurance for environmental liability, but this insurance may not provide adequate coverage against potential liabilities

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Employees

As of the date of this prospectus, we had seven full time employees. These employees are located in the U.S. and India.

From time to time, we also employ independent contractors, consultants, and temporary employees to support its operations. None of our employees are subject to collective bargaining agreements. We believe that our relations with our employees are good.

Properties

We have approximately 110 square feet of office space in Princeton, New Jersey under an operating service agreement that expires October 31, 2024, and is automatically renewed every 3 months.

We also lease approximately 3000 square feet of office and laboratory in New Delhi, India under an operating lease that expires on December 31, 2024 and approximately 1,500 square feet of laboratory in New Delhi, India under an operating lease that expires on December 31, 2024. We also have office space in Cambridge, Massachusetts under an office service agreement dated June 27, 2024 which is on a month-to-month basis.

Legal Proceedings

We are not currently a party to any material litigation, and we are not aware of any pending or threatened litigation against it that could have a material adverse effect on its business, operating results, or financial condition. The industry in which we operate is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various legal proceedings from time to time.

Corporate Information

We were originally incorporated in the state of Delaware in August 2017. Our principal executive offices are located at 100, Overlook Center, 2nd Floor, Princeton NJ 08540 USA, and its telephone number is 973-832-8147. Our website address is www.vyometx.com. The information on, or that may be accessed through, our website is not incorporated by reference into this Registration Statement on Form S-1 and should not be considered a part of this Registration Statement on Form S-1.

VYOME MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis of financial condition and results of operations is to allow investors to view the Company from management's perspective, considering items that would have a material impact on future operations. This discussion should be read in conjunction with our consolidated financial statements for the year ended December 31, 2023, and 2022 and for the nine months ending September 30, 2024, and 2023 and related notes thereto included elsewhere in this proxy/information statement- prospectus. This discussion contains forward-looking statements based upon current plans, expectations and beliefs that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in or implied by these forward-looking statements as a result of several factors, including those discussed in the sections captioned "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements."

Overview

The Company is a Cambridge, MA/Princeton, NJ/ New Delhi, India-based clinical-stage specialty pharmaceutical company working to treat immune-inflammatory and rare diseases of unmet need with next generation therapeutic solutions with a business advantage of the US-India innovation corridor. The lead program VT-1953, is a topical gel that is being developed to treat signs and symptoms of malignant fungating wounds, a potentially orphan drug designation program. The Company is planning to have discussions with the Food & Drug Administration (FDA) on a pivotal trial protocol in the fourth quarter of 2024. The Company also has a Pre-Investigative New Drug application stage ophthalmic drops program, a potentially orphan drug program, VT-1908, a repurposed immune modulator to treat steroid sparing anterior uveitis. Another late clinical stage program, VB1953, for moderate to severe acne, has successfully completed its Phase II clinical trial and this program is Phase 3 ready. The Company may experience delays in the conduct of clinical trials of its candidates. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Any delays in completing the Company's clinical trials will increase its costs, slow down its product development, timeliness and approval process and delay its ability to generate revenue.

The Company also has commercialized two novel reformulated topical anti-fungal products based on the technology platform of Molecular Replacement Therapeutics ("MRT") in India — a dandruff lotion and shampoo. The Company has entered into a licensing and marketing agreement with Sun Pharma Laboratories Limited ("Sun Pharma") to sell such topical anti-fungal products in India. The Company used third-party entities to manufacture the products. During 2023, the Company amended its arrangement with Sun Pharma such that the Company will no longer be responsible for purchasing and selling inventory of the products, but instead will receive a net service fee payment for sales of such products made by Sun Pharma.

The Company operates in two segments, biotechnology and pharmaceutical. Our biotechnology segment comprises our operations around our VT-1953, VT-1908 and VB-1953 programs that are in development and our pharmaceutical segment comprises of our antifungal products.

Since inception, our operations have focused on organizing and staffing our biotechnology segment, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates, undertaking preclinical and clinical studies and manufacturing. We do not have any products approved for sale and have not generated any revenue from product sales from the biotechnology segment. Our pharmaceutical segment represents the operations of a legacy business, and after the 2023 amendment to our licensing agreement with Sun Pharma, requires little further effort on our part. From inception through September 30, 2024, we raised an aggregate of approximately $37.5 million of gross proceeds through the sale and issuance of our preferred stock and common stock an $2.7 million from the sale of convertible notes including the new bridge notes issues in the quarter ending September 30, 2024.

Since inception, we have incurred significant operating losses. Our net loss was $720,370 and $1,268,816 for the years ended December 31, 2023, and 2022, respectively. We had an accumulated deficit of $53,927,896 as of December 31, 2023. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacturing of our drug product and drug supply, regulatory approval for our current and future product candidates, maintenance and expansion of our intellectual property portfolio, hiring of additional research, development and business personnel and operations as a public company.

We will not generate revenue from product sales for our biotechnology segment unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition.

The report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2023, included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. See Note 1 to our annual consolidated financial statements appearing in this proxy/information statement-prospectus for additional information on our assessment.

As of December 31, 2023, we had a cash balance of $16,647 and have operated under an austerity plan for several years. As of September 30, 2024, we had a cash balance of $48,872. We sold approximately $270,000 in convertible notes from July 1, 2024 through September 30, 2024. We believe that our existing cash, funds we may raise through the issuance of additional convertible notes and with the anticipated net proceeds from the Concurrent Financing, described below, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

Recent Developments

Merger Agreement

On July 8, 2024, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with ReShape Lifesciences Inc., and Raider Lifesciences Inc., a direct, wholly-owned subsidiary of ReShape. Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions specified therein, Merger Sub shall be merged with and into Vyome, with Vyome surviving as a subsidiary of ReShape (the "Merger").

Concurrent Financing

Simultaneously with the execution of the Merger Agreement, ReShape, Vyome, and Vyome's wholly-owned subsidiary Vyome Therapeutics Limited ("Vyome India") entered into agreements with certain accredited investors, pursuant to which the investors have agreed to purchase up to $7.3 million in securities of ReShape, Vyome and Vyome India (the "Concurrent Financing"). As part of the Concurrent Financing, certain accredited investors have agreed to purchase up to $5.8 million in shares of common stock of the Combined Company immediately following completion of the Merger. The price per share for the common stock of the Combined Company will be calculated as a 30% discount to the price per share of the common stock for the agreed upon valuation of the combined company obtained by dividing (i) the sum of $130,000,000 and ReShape Net Cash by (ii) the sum of Total ReShape Outstanding Shares and Vyome Merger Shares. ReShape and the investors also entered into registration rights agreements which provides for certain registration rights to the investors including the filing of a registration statement, that includes the

shares of common stock purchased by the investors, within 45 days of the closing of the Merger. Simultaneously with the execution of the subscription agreements, Vyome entered into a securities purchase agreement with each investor pursuant to which Vyome issued to each investor a convertible promissory note in the principal amount equal to 5% of such investor's total agreed upon investment amount, which convertible notes will bear interest at 8% per annum and immediately prior to completion of the Merger will convert into a number of shares of common stock of the Combined Company equal to 100% of the outstanding principal and interest of the convertible notes divided by the price per share of common stock of the Combined Company to be purchased in the Concurrent Financing, as set forth above. ReShape and the investors are executing and delivering the subscription agreements in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended.

Expected Use of Proceeds

The Combined Company currently expects to use the approximately $6.5 million in cash, cash equivalents, and marketable securities immediately after the completion of the Merger for up to one year and after deducting estimated transaction expenses as follows:

- approximately $2.75 million for continued research and development towards regulatory work and pivotal trial of VT-1953 for the therapeutic indication of treating malodor in malignant fungating wounds;
- approximately $1.00 million for continued advancement of VT-1908 into IND filing and Phase1/2 trial; and
- the remainder for general corporate purposes.

The specific allocation of the expected cash, cash equivalents, and marketable securities immediately after the completion of the Merger towards specific programs will depend on, among other things, results from the Combined Company's research and development efforts for each program, the timing and success of its preclinical and clinical studies and the timing and outcome of regulatory submissions. However, based on the Combined Company's current planned use of the cash, cash equivalents, and marketable securities immediately after the completion of the Merger and after deducting estimated transaction expenses, such funds are estimated to be sufficient to enable the Combined Company to fund its operating expenses and capital expenditure requirements through the initiation of pivotal trial for VT-1953 product candidate for one year after Merger Closing (subject to submission of regulatory filing and authorization to proceed), as well as other potentially value-creating milestones for VT-1908 in 2025. This estimate is based on assumptions that may prove to be wrong, and the Combined Company could use its expected capital resources sooner than currently anticipated.

The Combined Company does not expect the proceeds from the completion of the Merger (including the Concurrent Financing) and Vyome's existing cash, cash equivalents, and marketable securities will be sufficient for it to advance any of its programs through regulatory approval, and the Combined Company will need to raise additional capital to complete the development and potential commercialization of any of its programs. The Combined Company may also use a portion of its cash, cash equivalents, and marketable securities, to acquire, in-license or invest in products, technologies, or businesses that are complementary to its business. The amounts and timing of actual expenditures will depend on numerous factors, including the progress of preclinical development efforts, operating costs, and other factors described under "*Risk Factors*" in this proxy/information statement-prospectus.

The expected use of proceeds represents current intentions based on present plans and business conditions. As of the date of this proxy statement/prospectus, the Combined Company cannot predict with complete certainty all of the particular uses for the expected cash that will be available upon the closing of the Merger or the actual amounts that it will spend on the uses set forth above.

Components of Results of Operations

Although we operate in two segments, all of our revenue relates to the pharmaceutical segment, and substantially all of our costs relate to the biotechnology segment. See the "Segments" footnote in our Financial Statements.

Revenue

We recorded sales of pharmaceutical products until October 2023. During 2023, the Company amended its arrangement with Sun Pharma such that the Company will no longer be responsible for purchasing and selling inventory of the dandruff lotion and shampoo, but instead will receive a net service fee payment for sales of such products made by Sun Pharma. These payments are recorded as service fee revenue in the period earned. Such revenues are part of our pharmaceutical segment. We have occasionally received payments for the license of our products to Sun Pharma, but do not expect to receive any significant further payments under such licenses except royalties.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, and (ii) cost of goods sold and (iii) general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts and preclinical and clinical studies under our research programs, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense for our research and development personnel;
- costs of funding research performed by third parties that conduct research and development and preclinical and clinical activities on our behalf;
- costs of manufacturing drug product and drug supply related to our current or future product candidates;
- costs of conducting preclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs of maintaining our laboratory, including purchasing laboratory supplies and non-capital equipment used in our preclinical studies;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical and clinical studies or other services performed.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if they are approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;

- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as we commence clinical trials and continue the development of our current and future product candidates. However, we do not believe that it is possible, at this time, to accurately project expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Cost of Goods Sold

Cost of goods sold represents the costs to obtain products from the third-party manufacturer of our pharmaceutical products sold to Sun Pharma. Pursuant to the 2023 amendment to our arrangement with Sun Pharma, we are no longer responsible for purchasing and selling inventory of the products, but instead, receive only a net service fee.

General and Administrative Expenses

General and administrative expenses include salaries and other compensation-related costs, including stock-based compensation, for personnel in executive, finance and accounting, business development, operations and administrative roles. Other significant costs include insurance costs, professional fees, travel costs, facility and office-related costs, not included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including our future clinical programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside service providers, among other expenses. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

We also anticipate increased expenses associated with being a public company upon consummation of the Merger, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the SEC, and listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums, and investor relations costs.

Interest Expense

Interest expense results from the stated interest rates under our convertible notes. Borrowings under the notes carry an 8% coupon interest rate.

Fair value adjustment

We record our convertible notes at fair value. Changes in the fair value of the convertible notes are recognized as a component of other income.

Comparison of the Years Ended December 31, 2023, and 2022

Results of Operations

The following table summarizes our results of operations for the years presented:

	For the Years ended December 31,		
	2023	2022	Change
Revenues			
Revenue	$ 415,940	$ 382,865	$ 33,075
Cost of goods sold	(133,408)	(236,746)	103,338
Gross profit	282,532	146,119	136,413
Operating expenses:			
Research and development	755,805	826,602	(70,797)
General and administrative	294,445	423,700	(129,255)
Total operating expenses	1,050,250	1,250,302	(200,052)
Loss from operations	(767,718)	(1,104,183)	(336,465)
Other income (expense):			
Fair value adjustment	214,059	(148,424)	362,483
Other	(1,581)	122,290	(123,871)
Interest expense	(164,680)	(124,981)	(39,699)
Net loss	$ (719,920)	$(1,255,298)	$ 535,378

Revenue

The Company derives revenues from the sale of products, including royalties related to sales of such products and from the license of our technology. Substantially all revenues for the years ended December 31, 2023, and 2022 were derived from one customer, Sun Pharma, based in India. During 2023, the Company amended its arrangement with Sun Pharma such that the Company will no longer be responsible for purchasing and selling inventory of the products, but instead will receive a net service fee payment for sales of such products made by Sun Pharma. Revenues for the years ended December 31, 2023, and 2022 are summarized as follows:

	December 31, 2023	December 31, 2022
Sale of dandruff lotion and shampoo	$221,351	$373,995
Licensing and milestone fees	121,100	—
Service fee for arrangements for sale of dandruff products	67,762	—
Royalty income related to above product sales	5,727	8,870
Total	$415,940	$382,865

Research and Development Expenses

Research and development expenses were $294,445 and $423,700 for the years ended December 31, 2023, and 2022, respectively. The decrease of $129,255 was primarily due to:

- Our compound VB-1953 completed its Phase 2 clinical trial for inflammatory acne in 2020 and we have been focused since then on organizing our plans to commence the pivotal trial of the same

compound for a different program, VT-1953, for treating malodor in malignant fungating wounds, once sufficient funding is secured.

- Our pre-clinical programs have proceeded slower than we expected due to a lack of available funding.

General and Administrative Expenses

General and administrative expenses were $755,805 and $826,602 for the years ended December 31, 2023, and 2022, respectively. The decrease of $70,797 was primarily due to the reduction of administration expenses and of manpower caused by the change in our relationship with Sun Pharma and the slowing of our pre-clinical research programs, due to a lack of funding.

Interest expense

Interest expense was $164,680 and $124,981 for the years ended December 31, 2023, and 2022, respectively. The increase was driven by additional convertible note borrowings by the Company.

Fair value adjustment

The fair value adjustment was $214,059 and $(148,424) for the years ended December 31, 2023, and 2022, respectively. The increase of $362,483 was primarily due to changes in the assumptions used for the year ended December 31, 2023, to calculate the fair value, including the likelihood and timing of a "qualified financing" which would trigger a conversion of the convertible notes, under their terms.

Other income

The Company has earned approximately $103,400 in service export incentive in India from the Indian government authorities during the year ended December 31, 2022. This was earned by the Company's Indian subsidiary because of the export of services to the US based parent company under the rules and regulations of the export promotion incentives announced by the Indian government from time to time. No such amounts were earned in 2023.

Cash Flows

The following table summarizes our cash flows for the years indicated:

	For the years ended December 31,		
	2023	2022	Change
Net cash provided by (used in):			
Operating activities	$(563,983)	$(362,879)	$(201,104)
Investing activities	201	68	133
Financing activities	122,349	752,651	(630,302)
Other	(164)	208	(372)
Net (decrease) increase in cash	$(441,597)	$ 390,047	$(831,644)

Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was $563,983, consisting primarily of net losses of $719,920 less the non-cash charge for interest expense of $162,741 and an increase in accrued compensation and post-employment benefits of $204,283, offset by the gain on fair value adjustment of convertible debt of $214,059. During the year ended December 31, 2022, net cash used in operating activities was $362,879, consisting primarily of net losses of $1,255,298 less the non-cash charge for interest and the loss on the fair value adjustment of convertible note debt of $148,424 and $122,933, respectively, an increase in accrued compensation and post-employment benefits of $211,433, a decrease in prepaid expenses and other assets of $205,945 and an increase in accounts payable of $104,209. During 2023 and 2022, we have primarily used the proceeds of the sale of our convertible notes to incrementally

develop our biotechnology products and prepare the Company for an offering of its securities and activities related thereto. We have operated under an austerity program for several years, delaying projects and payments until sufficient funds could be raised. We had approximately $17,000 of cash at the end of 2023.

Financing Activities

During the year ended December 31, 2023, cash provided by financing activities was $122,349, consisting primarily of net proceeds of $150,000 from the sale of convertible notes.

During the year ended December 31, 2022, cash provided by financing activities was $752,651, consisting primarily of net proceeds of $725,000 from the sale of convertible notes.

Comparison of the Nine months Ended September 30, 2024, September 30, 2023

Results of Operations

The following table summarizes our results of operations for the periods presented:

(Amount in USD)	January 01, 2024, to September 30, 2024	January 01, 2023, to September 30, 2023
Revenue		
Revenue	$ 195,516	$ 346,571
Cost of goods sold	(63,307)	(133,241)
Gross profit	**$ 132,209**	**$ 213,330**
Operating expenses		
Depreciation and amortization	13,483	16,425
Selling, general and administrative	727,336	606,594
Research and development expenses	255,645	251,498
Total operating expenses	**$ 996,464**	**$ 874,517**
Operating loss	(864,255)	(661,187)
Other income/(expense), net:		
Interest expenses	$ (153,229)	$(121,409)
Other income(loss), net	2,341	(1,759)
Fair value adjustment	(239,686)	327,773
Total other income, net	**(390,574)**	**204,605**
Net loss	**$(1,254,829)**	**$(456,582)**

Revenue

The Company derives revenues from the sale of products, including royalties related to sales of such products and from the license of its technology. Substantially all revenues for the nine months ended September 30, 2024, and 2023 were derived from one customer, Sun Pharma, based in India. During 2023, the Company amended its arrangement with Sun Pharma such that the Company will no longer be responsible for purchasing and selling inventory of the products, but instead will receive a net service fee payment for sales of such products made by Sun Pharma. Revenues for the nine months ended September 30, 2024, and 2023 are summarized as follows:

	Nine months ending September 30, 2024	Nine months ending September 30, 2023
Sale of Dandruff Lotion and Shampoo Trading	—	$221,449
Licensing and milestone fees	—	121,000
Service fee for arrangements for sale of Dandruff products	187,389	—
Royalty income related to above product sales	8,127	4,022
Total	$195,516	$346,571

Cost of goods sold expenses

The Company was buying and selling Dandruff lotion and shampoo until November 2023. Subsequently, the manufacturer engaged by the Company was asked to supply products directly to Sun Pharma and the Company started billing the service fee to Sun Pharma for arrangements for the supply of Dandruff products to them. The Company has incurred cost of goods sold expenses of $63,307 and $133,241 for the nine months ending September 2024, and 2023.

Research and Development Expenses

Research and development expenses were $255,645 and $251,498 for the nine months ended September 30, 2024, and 2023, respectively. The increase of $4,147 was primarily due to some additional research work done by our team.

General and Administrative Expenses

General and administrative expenses were $727,336 and $606,594 for the nine months ended September 30, 2024, and 2023, respectively. The increase of $120,742 was primarily due to the commencement of reverse merger process and related legal, accounting and auditing costs.

Interest expense

Interest expense was $153,229 and $121,409 for the nine months ended September 30, 2024 and 2023, respectively. The increase was driven by additional borrowings by the Company.

Fair value adjustment

The fair value adjustment expense/(income) was $(239,686) and $327,773 for the nine months ended September 30, 2024, and 2023, respectively. The increase of $567,459 was primarily due to changes in the assumptions used to calculate the fair value, including an increase in the likelihood and timing of a "qualified financing" whereby conversion of the convertible notes would occur during the 2025 period.

Other income

The other income/(expense) was $2,341and $(1,759) for the nine months ended September30, 2024 and 2023, respectively. The increase of $4,100was primarily due to changes in miscellaneous items.

Cash Flows

The following table summarizes our cash flows for the nine months indicated:

	January 1 2024, to September 30, 2024	January 1 2023, to September 30, 2023	Change
Net cash provided by(used in)			
Net cash used in operating activities	$(611,258)	$(489,644)	$(121,614)
Net cash used in investing activities	(1,482)	—	(1,482)
Net cash from financing activities	644,484	119,849	524,635
Other	479	4,372	(3,893)
Net increase/(decrease) in cash and cash equivalents	$ 32,223	$(365,423)	$ 397,646

Operating Activities

During the nine months ended September 30, 2024, net cash used in operating activities was $611,258, consisting primarily of our net loss of $1,254,829 less the non-cash charge for interest expense of $137,942 and an increase in accrued compensation and post-employment benefits of $175,593, offset by the loss on fair value adjustment of convertible debt of $239,686. During the nine months ended September 30, 2023, net

cash used in operating activities was $489,644, consisting primarily of net loss of $456,482 less the non-cash charge for interest of $119,751, an increase in accrued compensation and post-employment benefits of $173,738, a decrease in prepaid expenses and other assets of $40,587 and an increase in accounts payable of $35,970, partially offset by the gain on the change in fair value of our convertible debt of $327,773. We have primarily used the proceeds of convertible notes to prepare the company for the Merger and activities related thereto. We have operated under an austerity program for several years, delaying projects and payments until sufficient funds could be raised.

Financing Activities

During the nine months ended September 30, 2024, cash provided by financing activities was $644,484, consisting primarily of net proceeds of $613,542 from the convertible notes.

During the nine months ended September 30, 2023, cash provided in financing activities was $119,849, consisting primarily $150,000 from the convertible notes offset by $30,151 of the settling of advances from affiliates.

Liquidity and Capital Resources

Sources of Liquidity/Going Concern

Since our inception, we have funded our operations through the sale and issuance of preferred and common stock and convertible notes. From inception through September 30, 2024, we raised an aggregate of approximately $37.5 million in gross proceeds from sales of our equity securities (the last of such offering occurred in December 2018), and approximately $2.7 million in gross proceeds from our convertible notes.

In October 2020, we offered for sale an 8%, interest bearing convertible promissory note to investors, which provide for a three year term from the date of issuance, unless earlier converted. This has been our primary source of funding since 2020. We received $340,000 and $0 from the sale of our convertible notes during the six months ended June 30, 2024, and 2023, respectively. During 2023 and 2024, eight of our convertible notes, were extended by an additional year. In connection with such extension, the conversion rate was amended from 0.80 to 0.75 of the price paid by investors in a qualified offering, as defined in the convertible notes, and the liquidation preference, in the event the Company consummates a Deemed Liquidation Event, as defined in the Company's Certificate of Incorporation, was amended.

We have converted certain liabilities to vendors, employees and board members into equity instruments during 2024 — see further discussion below in the sections captioned "Accrued Compensation" and "CRO Contract."

The accompanying consolidated financial statements of December 31, 2023, and September 30, 2024, have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. Since our inception, we have not generated any revenue from our biotechnology products, and we have incurred significant operating losses. We have not yet commercialized any biotechnology products, and we do not expect to generate revenue from sales of any biotechnology product candidates for a number of years, if ever. As reflected in the accompanying consolidated financial statements, we have incurred recurring net losses since our inception. During the year ended December 31, 2023, we incurred a net loss of $719,920 and used cash in operations of $563,983 and had a stockholders' deficit of $6,085,172 as of December 31, 2023. During the nine months period ended September30, 2024, we incurred a net loss of $1,254,829 and used cash in operations of $611,258 and had a stockholders' deficit of $4,110,000 as of September 30, 2024. These factors raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional funds and implement our strategies, such as executing additional licensing contracts. The consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

The ability to continue as a going concern is dependent on the Company raising additional capital and attaining and maintaining profitable operations in the future to meet its obligations and repay liabilities arising from normal business operations when they come due. Since inception, we have funded our operations

primarily through equity and debt financings and licensing income and we expect to continue to rely on these sources of capital in the future.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing, or grant unfavorable terms in licensing agreements.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development, initiate and conduct preclinical studies and clinical trials, and seek marketing approval for our current and any of our future product candidates. In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution, which costs we may seek to offset through entry into collaboration agreements with third parties. Furthermore, we expect to incur additional costs associated with operating as a public company, upon consummation of the Merger Agreement. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our existing cash, together with the anticipated net proceeds from the Concurrent Financing, will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on a number of factors, including:

- the costs of conducting preclinical studies and clinical trials;
- the costs of manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities; and
- the costs of operating as a public company.

We believe that the net proceeds of the Concurrent Financing, together with our existing cash, will be sufficient to initiate the pivotal trial of our lead candidate, VT-1953, but will not be sufficient to complete the trial and or work on the other indications or the development of any other product candidate. Accordingly, we will be required to obtain further funding to further achieve our business objectives.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings and debt financings or other sources, such as potential collaboration

agreements, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the interests of our stakeholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of our stockholders. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through potential collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Bridge Loan and Convertible Notes

Commencing in October 2020, the Company began raising money through the issuance of compulsorily convertible promissory notes in a private placement offering of up to $2,132,000 through December 31, 2023, which was subsequently expanded to approximately $2.47 million and extended through June 30, 2024. No new notes were raised under this arrangement after June 2024.

The convertible notes bear interest at a rate of eight percent (8%) per annum, on a non-compounding basis, and are due and payable on the earlier of (i) the date upon which the convertible notes are converted into equity securities of the Company, pursuant to the conversion terms of the convertible notes, set forth therein, or (ii) at maturity, which is three (3) years from the date of issuance. The terms of the convertible notes provide for automatic conversion of the outstanding principal and any unpaid accrued interest in the event that the Company issues and sells shares of its equity securities to investors prior, to the maturity date of the convertible notes, for total proceeds to the Company of not less than $10,000,000, at a conversion price equal to the cash price per share paid for the equity securities by the investors in such financing transaction multiplied by 0.75 in the case of some of the convertible notes or 0.8 in the case of other convertible notes.

During 2023 and 2024, certain of our convertible notes, were extended by an additional year. In connection with such extension, the conversion rate was amended from 0.80 to 0.75 of the price paid by investors in a qualified offering, as defined in the convertible notes, and the liquidation preference, in the event the Company consummates a Deemed Liquidation Event, as defined in the Company's Certificate of Incorporation, was amended. All other terms of the convertible terms remained the same. The Company accounted for such extension as a modification of the debt instrument. In August 2024, two Convertible Notes with an aggregate principal plus accrued interest of $434,077 were converted in 111,616 shares of Series D preferred stock at $3.889 per share. No other Convertible Notes have been converted through September 30, 2024.

In July 2024, the Company began offering investors the opportunity to participate in a Securities Purchase Agreement (the "Concurrent Financing") providing investors the right to certain equity instruments and other equity rights, some of which are dependent upon the completion of the Merger. An aggregate of 18 investors agreed to participate in such financing through September 30, 2024, for an aggregate of approximately $7.3 million, of which approximately $413,542 was received through September 30, 2024, in the form of bridge notes. The bridge notes have similar terms to the above convertible notes except that there is a one-year maturity. The remainder large part committed funds will be placed in an escrow account six to seven days before the Merger, pending completion of the Merger, however, these funds have not been received as of September 30, 2024.

The fair value amount of the Company's convertible notes is summarized as follows:

	As of September 30, 2024	As of December 31, 2023
Current portion		
Conversion rate at 75%	$1,758,973	$1,356,796
Conversion rate at 80%	$ 545,877	$ 606,590
Total current portion	**2,304,850**	**$1,963,386**
Long Term portion		
Conversion rate at 75%	1,183,131	967,503
Conversion rate at 80%	—	—
Total Long term Portion	**$1,183,131**	**967,503**
Total	**$3,487,981**	**$2,930,889**

Interest expense on the above debt instruments was $137,942 and $119,751 for the nine months ended September 30, 2024, and 2023, respectively. The Company has elected to record the convertible note at fair value. Changes in the fair value of the Convertible Notes for the nine months ended September 30, 2024, and 2023 are summarized as follows:

	Nine months ended September 30, 2024	Nine months ended September 30, 2023
Balance, beginning of the period	$2,930,888	$2,832,205
Additional notes issued	613,542	150,000
Notes and accrued interest converted to preferred stock	(434,077)	—
Interest Accrued	137,942	119,751
Change in fair value	239,686	(327,773)
Total	**$3,487,981**	**$2,774,184**

The fair value of the convertible notes is classified within Level 3 of the fair value hierarchy, using the inputs below to calculate the fair value. The Company used a probability weighted scenario analysis to determine the fair value of the convertible notes. The risk-free rate used in the analysis is based on the yield on a US Government zero-coupon bond, interpolated for the period that corresponds to the time to liquidity as at the valuation date.

	September 30, 2024	December 31, 2023
Adjusted Interest rate	4.38% to 4.93%	4.87% to 5.50%
Time to Financing Date	3 – 4 months	8 – 10 months

Preferred stock

During the nine months ended September 30, 2024, the Company issued 432,041 shares of Series D preferred stock in connection with a CRO contract (see Note 13) and 111,616 upon conversion of debt (see Note 8).

As of September 30, 2024, and December 31, 2023, the Company has issued the following preferred stock:

Series	Number of shares issued as of September 30, 2024	Number of shares issued as of December 31, 2023	Conversion Price	Aggregate Liquidation Preference as of September 30, 2024	Aggregate Liquidation Preference as of December 31, 2023
Series seed	1,078,560	1,078,560	$0.83	$ 1,314,718	$ 1,260,811
Series A	2,592,080	2,592,080	$1.22	4,608,589	4,419,626
Series B	965,200	965,200	$2.47	3,481,589	3,338,836
Series B-1	1,480,560	1,480,560	$2.47	5,340,553	5,121,578
Series C	4,432,880	4,432,880	$2.64	17,105,642	16,404,271
Series C-1	530,040	530,040	$2.64	2,045,324	1,961,461
Series D	4,224,097	3,680,440	$3.89	22,674,382	20,086,235
Total	15,303,417	14,759,760		**$56,570,796**	**$52,592,818**

The significant terms of the preferred stock, are as follows:

Preferred stock carries an 8% cumulative preference dividend, payable when declared by the Board of Directors. No dividend has been paid on any series of preferred stock as of September 30, 2024. As of September 30, 2024, and December 31, 2023, cumulative dividends in arrears for all classes' preferred shares were approximately $17,289,000 and $14,991,000, respectively.

Each share of preferred stock shall be convertible at the option of the holder, without the payment of additional consideration, into units of common stock at the conversion price as defined in the shareholders' agreement. The conversion price is subject to adjustment in the event of subsequent issuance of common stock at a lower price than the original conversion price. Each series preferred stock is mandatorily convertible into common stock at the conversion price as defined in the shareholders' agreement on the occurrence of an initial public offering (IPO).

In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, all classes of preferred stockholders would be entitled to receive, in preference to common shareholders, an amount equal to the original issue price plus accrued and unpaid dividends. All series of preferred stock rank pari passu with each other in terms of liquidation preference except series B1 and C1. Part of the amount invested by series B1 and C1 preferred stock as mentioned in the shareholders' agreement ranks junior to other preferred stockholders, however, rank pari passu with each other. After the liquidation preference payments to all classes of preferred stockholders have been met, preferred shareholders have unlimited right to participate on a prorated basis with common shareholders.

Holders of the preferred stock shall be entitled to elect 5 members of the Board of Directors and also hold certain protective rights with respect to significant corporate transactions as defined. Each holder of common stock shall be entitled to one vote in respect of each share held.

Accrued compensation

Accrued compensation payable to the chief executive officer, a board member/consultant of the Company and another consultant was $1,115,232 as of December 31, 2023. In June 2024, these individuals to forgo accrued compensation of $1,115,232 as of December 31, 2023, in exchange for the issuance of stock options for the purchase of 643,030 shares of common stock. The Company accounted for this debt extinguishment as a capital contribution since the liability was with related parties.

Accordingly, the difference between the liability extinguished of $1,115,232 and the fair value of the stock options issued ($379,950 as determined using a Black Scholes model) of $735,282 is considered a capital contribution, collectively included in the condensed consolidated statement of stockholder's deficit as "Issuance of shares in settlement of accrued liability".

CRO contract

In December 2018, the Company entered into an agreement with a Contract Research Organization ("CRO") for services to be rendered with respect to the phase 2B clinical trials for the Company's VB-1953 product. As of December 31, 2023, the outstanding balance due to the CRO was approximately $1,680,210. Also, pursuant to the July Agreement, the parties agreed that if the balance remained outstanding as of March 2021, then such balance could convert to Series D preferred stock of the Company at Series D preferred conversion price as of the July Agreement date. During 2022, the Company and the CRO agreed by signing a definitive agreement to convert the amount owed of $1,680,210 into 432,041 shares of Series D preferred stock (based upon the then estimated fair value of such shares). However, the shares were not issued. At that time, in order to issue the shares, the Company would have had to authorize additional shares of its Series D preferred stock in order to consummate the transaction, and accordingly, as of December 31, 2023, $1,680,210 was recorded as a liability to be settled in equity in the consolidated balance sheet. In June 2024, the Company increased its authorized shares of preferred stock and issued the 432,041 shares of Series D preferred stock to settle this liability.

Due to Affiliates

The amount outstanding to two of our board directors as of September 30, 2024, is $97,831, which is included in the "due to affiliates" in the consolidated balance sheet. There is no interest or scheduled repayment dates of such advances.

Contractual Obligations and Commitments

We enter into agreements in the normal course of business for sponsored research, preclinical studies, contract manufacturing, and other services and products for operating purposes, which are generally cancellable upon written notice.

Any Licenses, employment agreements, CRO agreements or other commitments

On January 1, 2024, we entered into a one-year lease for office and laboratory space in Delhi, India, mutually renewable every year. The commencement date and the first obligation to pay rent was January 2024, with annual rent at approximately $35,000 per year. We have the option to renew such lease upon mutually agreed terms. We have offices in Princeton NJ, and Cambridge MA, on short-term rentals.

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore, we believe that our non-cancelable obligations under these agreements will not be material.

We also have employment agreements with certain employees and consulting agreements which require the funding of a specific level of payments, if certain events, such as a change in control, termination without cause or retirement, occur. We also have an agreement on Resignation and Separation Letter dated January 11, 2021 Craig Tooman, a past employee to pay certain amount on change of control.

Controls and Procedures

A company's internal control over financial reporting is a process designed by, or under the supervision of, that company's principal executive and principal financial officers, or persons performing similar functions, and effected by that company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness in future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate.

We have concluded that there were material weaknesses in internal control over financial reporting. Historically, we were a private company that had not previously been audited and had maintained a

complement of resources with various levels of accounting knowledge, experience, and expertise that are not commensurate with our prospective financial reporting needs. These material weaknesses relate to the fact that we do not maintain a comprehensive policies and procedures manual designed to establish internal controls over financial reporting to reduce the risk of publishing materially misstated financial statements, as well as define responsibilities and segregate incompatible duties to reduce the risk of unauthorized transactions. Collectively, this could result in difficulties in meeting our internal reporting needs and our external reporting requirements and assessing the appropriate accounting treatment for various events and/or circumstances.

We have initiated various remediation efforts, including the hiring of additional financial personnel/ consultants with the appropriate public company and technical accounting expertise and other actions that are more fully described below. As such remediation efforts are still ongoing, we have concluded that the material weaknesses have not been fully remediated. Our remediation efforts to date have included the following:

We have assessed our current accounting personnel, financial reporting, and information system environments and capabilities. Based on our preliminary findings, we have found these resources and systems lacking and have concluded that these resources and systems will need to be supplemented and/or upgraded. We are searching for a Chief Financial Officer and, thereafter will implement additional accounting procedures and controls.

We engaged external consultants with public company and technical accounting experience to facilitate accurate and timely accounting closes and to accurately prepare and review our financial statements and related footnote disclosures. We plan to retain these financial consultants until such a time that our internal resources have been upgraded and the required financial controls have been fully implemented.

The actions that have been taken are subject to continued review, implementation, and testing by management, as well as audit committee oversight. While we have implemented a variety of steps to remediate these weaknesses, we cannot assure you that we will be able to fully remediate them, which could impair our ability to accurately and timely meet our public company reporting requirements.

Notwithstanding the assessment that our internal controls over financial reporting are not effective and that material weaknesses exist, we believe that we have employed supplementary procedures to ensure that the consolidated financial statements contained in this filing fairly present our financial position, results of operations, and cash flows for the reporting periods covered herein in all material respects.

Critical Accounting Policies and Significant Judgments and Estimates

Convertible Promissory Notes

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with *Topic 815* "*Derivatives and Hedging*" ("ASC 815") of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). The accounting treatment of derivative financial instruments requires that the Company record any bifurcated embedded features at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded in earnings each period as non-operating, non-cash income or expense. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Bifurcated embedded features are recorded at their initial fair values which create additional debt discount to the host instrument.

We have elected to account for the convertible notes to a shareholder using the fair value option in accordance with the guidance contained in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 825-10-25. The fair value option provides an option to elect fair value as an alternative measurement for selected financial assets, financial liabilities, unrecognized firm commitments, and written loan commitments. See Note 4 for additional information. Our company accounted for the fair value of the stock options issued in connection with the note payable to the Chairman as additional

interest expense on the grant date, using the same methodology to determine the fair value of the stock option as discussed in the share-based compensation policy footnote below.

Fair value measurements

FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*" ("ASC 820"), defines fair value, the methods used to measure fair value and the expanded disclosures about fair value measurements. Fair value is the price received to sell an asset or paid to transfer a liability in an orderly transaction between the buyer and the seller at the measurement date. In determining fair value, the valuation techniques consistent with the market approach, income approach and cost approach shall be used to measure fair value. ASC 820 establishes a fair value hierarchy for inputs, representing the assumptions the buyer and seller use in pricing the asset or liability. These inputs are further defined as observable and unobservable inputs. Observable inputs are those that the buyer and seller would use in pricing the asset or liability based on market data obtained from sources independent of our company. Unobservable inputs reflect our company's assumptions about the inputs the buyer and seller would use to price the asset or liability developed based on the best information available in the circumstances.

The carrying value of the Company's accounts payable approximates its fair value because of the short-term nature of these financial instruments. The note payable — related party is reported at fair value as the Company elected the fair value option for such note.

The fair value hierarchy is categorized into three levels based on the inputs as follows:

- Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that our company has the ability to access. Valuation adjustments and block discounts are not being applied. Since valuations are based on quoted prices that are readily and regularly available in an active market, the valuation of these securities does not entail a significant degree of judgment.
- Level 2 — Valuations based on (i) quoted prices in active markets for similar assets and liabilities, (ii) quoted prices in markets that are not active for identical or similar assets, (iii) inputs other than quoted prices for the assets or liabilities, or (iv) inputs that are derived principally from or corroborated by the market through correlation or other means.
- Level 3 — Valuations based on unobservable inputs and significant to the overall fair value measurement.

Determination of the Fair Value of Equity-Based Awards

We estimate the fair value of stock option awards granted using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and subjective assumptions we make, including expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we base the estimate of expected stock price volatility on the historical volatility of a representative group of publicly traded companies for which historical information is available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumption. We use the simplified method to calculate the expected term for options granted to employees and directors. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual term. The risk-free interest rate is based on a U.S. treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero, as we have never paid dividends and do not have current plans to pay any dividends on our common stock. We determine the fair value of common stock awards based on the fair value of our common stock on the date of grant.

As there has been no public market for our common stock, the estimated fair value of our common stock has been approved by our board of directors, with input from management, as of the date of each award grant, considering our most recently available sale of our common stock to independent investors and our board of directors' assessment of additional objective and subjective factors deemed relevant that may have changed from the date of the most recent determination through the date of the grant. The additional

objective and subjective factors considered by our board of directors in determining the fair value of our common stock included the following:

- the prices of our common stock and preferred stock sold to outside investors in arm's length transactions, if any, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock;
- the progress of our research and development efforts, including the status of preclinical studies and planned clinical trials for our product candidates;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the valuation of publicly traded companies in the biotechnology industry, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event, such as an IPO or a sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biotechnology industry.

The assumptions underlying our board of directors' valuation determinations represented our board's best estimates, which involved inherent uncertainties and the application of our board's judgment. As a result, if factors or expected outcomes had changed or our board of directors had used significantly different assumptions or estimates, our equity-based compensation expense could have been materially different. Following the completion of this offering, our board of directors will determine the fair value of our common stock based on the quoted market prices of our common stock.

Inflation

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2023, or 2022 or through September 30, 2024.

RISKS RELATED TO VYOME

In this subsection, "our", "we", "Company" or "Vyome" refers to Vyome Therapeutics, Inc. and its subsidiaries.

Risks Related to Vyome's Limited Operating History, Financial Condition and Capital Requirements

We have a limited operating history and have not taken a product through to commercialization.

We are a clinical-stage company with limited operating history. To become and remain cash flow positive and viable, we must develop (alone or in partnership(s)) and eventually commercialize (alone or in partnership(s)) a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including establishing our business model and key third-party relationships, completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for this product candidate, manufacturing, marketing and selling those products for which we (either alone or in partnership) may obtain marketing approval, satisfying any post-marketing requirements and otherwise monetizing the product, for example by selling or licensing the asset or the company.

Our products are not approved for commercial sale except for 2 products in India for sale by the subsidiary. Since our inception in August 2017, we have incurred significant operating losses and have utilized substantially all of our resources to date planning development of our product candidates, VT-1953, VT-1908 and VB-1953, Molecular Replacement Therapeutics ("MRT") technology based antifungal products and other assets under early stages of development (the "Vyome Assets") and organizing and staffing our company and providing other general and administrative support for our initial operations. We have no significant experience as a company in initiating, conducting or completing preclinical or clinical trials, including global late-stage clinical trials. As is widespread practice in the life sciences industry, we would be unlikely to physically conduct those trials ourselves, rather we would engage a third-party clinical trials organization. We cannot be certain that our planned preclinical and clinical trials will begin or be completed on time or at all. Furthermore, we cannot be certain whether our planned preclinical and clinical trials will be on budget or have significant cost overruns. We cannot predict whether the product will have the desired activity in the clinical trials or whether any side effects will be tolerable. In addition, we have not yet demonstrated an ability to obtain marketing approvals, manufacture a product to commercial scale or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to, or arrange for our third-party contractors to:

- timely file and gain acceptance of investigational new drug applications for our programs in order to commence planned clinical trials or future clinical trials;
- successfully enroll subjects in, and complete, our planned clinical trials;
- successfully start and complete our planned preclinical and clinical studies for the VT-1953 and VT-1908 programs;
- initiate and successfully complete all safety and efficacy studies required to obtain U.S. and foreign regulatory approval for the Vyome Assets, and additional clinical trials or other studies beyond those planned to support the approval and commercialization of VT-1953, VB-1953 and VT-1908;
- identify the proper human dose;
- successfully manage the prevalence, duration and severity of potential side effects or other safety issues experienced with the Vyome Assets, if any;
- obtain a positive readout from the clinical trials regarding therapeutic activity;
- obtain data and review any comments to our development plans for VT-1953, VB-1953 and VT-1908, which may delay our ability to perform diligence, development and commercialization;
- successfully demonstrate to the satisfaction of the FDA, EMA, or similar foreign regulatory authorities the safety and efficacy and acceptable risk to benefit profiles of VT-1953, VB-1953 and VT-1908;

- obtain the timely receipt of necessary marketing approvals from the FDA, EMA and similar foreign regulatory authorities;
- establish commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- position our product to effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement for our product;
- maintain a continued acceptable safety profile of VT-1953, VB-1953 and VT-1908 following approval;
- enforce and defend our intellectual property rights and claims; and
- obtain and maintain patent and trade secret protection or regulatory exclusivity for the Vyome Assets.

Furthermore, third parties may have or allege that they have intellectual property rights that block our commercial activities, and we may need to seek a license, which may not be available or may not be available at a reasonable price. We may also have a contractual dispute, which may take significant resources, including the management team's time, to resolve.

Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, if any, the extent of any further losses or if or when we might achieve profitability. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history or track record of relative success. We may never succeed in these activities and, even if we succeed in commercializing the Vyome Assets, we may never generate revenue that is significant enough to justify the investment in its development, achieve profitability or otherwise successfully monetize the product. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we may continue to incur substantial research and development and other expenditures to develop and market any additional product candidates. Our failure to become and remain profitable or otherwise successfully monetize the product could decrease the value of our shares and impair our ability to raise capital, reduce or eliminate our research and development efforts, expand our business or continue our operations. Further, we may encounter unexpected expenses, challenges and complications from known and unknown factors such as a global pandemic.

We have incurred losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from the Vyome Assets and may never generate revenue or become profitable.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront costs and capital expenditures over a multi-year timeframe, and ultimately a risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. Such factors can be binary in effect, with development halted should any such factor arise. We have no products approved for commercial sale, we have not generated any revenue to date, and we continue to incur research and development, and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval from the FDA, EMA and similar foreign regulatory authorities of, and then successfully commercialize, the Vyome Assets in one or more indications in one or more territories. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we are unable to raise further capital in the near-term, or partner with third parties that fund all or the vast majority of our costs and capital expenditures, then we may be unable to continue operations. We do not expect to generate sufficient revenue through any

means to fund our operations in the near-term. We cannot assure you that any additional financing that we are able to raise would not have a dilutive impact on your ownership interest in the post-Merger company.

We have incurred net losses in each period since our incorporation in August 2017. Our net losses were $5.4 million for the nine months ended September 30, 2024. We expect to continue to incur significant losses for the foreseeable future. Even after finding a means to fund the foreseeable, and unforeseeable, costs to develop our product, thereafter, the progress of our development, and the clinical results achieved, will affect, positively or negatively, the value of our company and accordingly our ability to raise capital. We will continue to not be profitable even if those results are favorable. Favorable results may increase our value, increasing our ability to raise capital. Unfavorable results are likely to decrease our value and could impair our ability to raise more capital, which is necessary to maintain our research and development efforts, expand our business and/or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

Our recurring losses from operations and financial condition could raise substantial doubt about our ability to continue as a going concern.

Without giving effect to the anticipated net proceeds from the merger and Concurrent Financing Agreements, we do not believe our existing cash and cash equivalents will be sufficient to fund all of our anticipated operating expenses, including clinical trial expenses, and capital expenditure requirements. Until such time, if ever, as we are able to successfully develop and commercialize the Vyome Assets, we expect to fund our operations through the sale of equity, debt, borrowing under credit facilities or through potential collaborations with other companies or other strategic transactions.

We will need to raise additional capital to finance our operations, which we may not be able to do on acceptable terms or at all. If we are unable to raise additional capital, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. After the consummation of the Merger, in our own required quarterly assessments, we may continue to conclude that there is substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Our ability to use net operating losses ("NOL") carryforwards may be limited.

Our ability to use our federal and state NOL carryforwards to offset potential future taxable income is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether we will generate sufficient taxable income to use all of our NOL carryforwards. As of December 31, 2023, Vyome had U.S. federal net operating loss carryforwards of approximately $15.7 million. Of the total U.S. federal net operating loss carryforwards at December 31, 2023, losses generated beginning in 2020 will carryover indefinitely. Vyome had state net operating loss carryforwards of $15.7 million at December 31, 2023, and had foreign net operating loss carryforwards of approximately $8 million at December 31, 2023. Net operating loss carryforwards of Vyome are subject to review and possible adjustment by the taxing authorities. With certain exceptions (e.g. the net operating loss carryforwards), Vyome is no longer subject to U.S. federal, state or local examinations by tax authorities for years prior to 2020. There are no tax examinations currently in progress.

Vyome's ability to utilize its net operating loss carryforwards, tax credits, and built-in items of deduction, including capitalized start-up costs and research and development costs, has been, and may continue to be substantially limited due to ownership changes. These ownership changes limit the amount of net operating loss carryforwards, credits and built-in items of deduction that can be utilized annually to offset future taxable income. In general, an ownership change, as defined in IRC Section 382, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the

outstanding stock of a company by certain stockholders or public groups. Due to the valuation allowance against deferred tax assets at December 31, 2023, the net effect of any further limitation will have no impact on results of operations.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, a vendor on which we are reliant could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any critical vendor bankruptcy or insolvency, or any breach or default by a critical vendor, or the loss of any significant vendor relationships, may have a material adverse impact on our business.

Previously, we recorded a non-cash indefinite-lived intangible and definite-lived assets impairment loss, which significantly impacted our results of operations, and we may be exposed to additional impairment losses that could be material.

We conduct our annual indefinite-lived intangible assets impairment analysis during the fourth quarter of each year or when circumstances suggest that an indicator for impairment may be present. Previously, we performed a qualitative impairment analysis of the in-process research and development. Due to delays in the clinical trials experienced, we revised its expectations of when revenues would commence for the Vyome Assets, thus reducing the projected near-term future net cash flows related to the Vyome Assets. During the quarter ended December 31, 2020, we stopped the clinical trials for the Vyome Assets and closed out the previous trials that occurred, as significant additional clinical work and cost would be required to achieve regulatory approval for the Vyome Assets. While Vyome and its subsidiaries have not recorded an impairment, in the future, we may have additional impairments requiring us to record an impairment loss related to our remaining finite-lived intangible assets and other investments, which could also have a material adverse effect on our results of operations.

If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts.

Developing biopharmaceutical products is a very long, time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval from the FDA, EMA, and similar foreign regulatory authorities for the Vyome Assets. Even if anyone of the Vyome Assets are

approved for commercial sale, we anticipate incurring costs associated with sales, marketing, manufacturing and distribution activities to launch the Vyome's Assets. Our expenses could increase beyond expectations if we are required by the FDA, EMA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of the Vyome's Assets. Our future capital requirements depend on many factors, including factors that are not within our control. Based on our current operating plan, we believe our existing cash, cash equivalents and short-term marketable securities, will be sufficient to fund our operations until the first half of 2025, after giving effect to the anticipated net proceeds from the merger and the Concurrent Financing. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

We do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our shareholders or the failure to obtain such financing may restrict our operating activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a shareholder. Debt financing may result in the imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to the Vyome Assets, or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by potential worsening global economic and political conditions and volatility in the credit and financial markets in the United States and worldwide, which could be exacerbated by, among other factors, the COVID-19 pandemic and/or the ongoing war between Russia and Ukraine and the conflicts in the Middle East. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Due to the significant resources required for the development of VT-1953 and VT-1908, we must prioritize the pursuit of treatments for certain indications. We may expend our limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success.

We intend to develop therapies for patients with serious immune system disorders. In particular, we are developing a portfolio of therapeutic indications for VT-1953 and VT-1908 and due to our limited financing, are initially focused on the development of VT-1953 in treating malodor in malignant fungating wounds where we plan to initiate a Phase 3 trial subject to FDA approval of the protocol and development of VT-1908 for uveitis where we plan to initiate IND enabling studies followed by Phases 1 and 2. In the event that we are required to limit our development plan for VT-1953 and/ or VT-1908, we may be unable to initiate clinical trials with the same scope that we otherwise intended to pursue, or the geographies in which we initiate such trials.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular indications may not lead to the development of any viable commercial product and may divert resources away from opportunities for other indications that later prove to have greater commercial potential or a greater likelihood of success. The primary end points for the Phase 3 trial of VT-1953 for the therapeutic indication of treating malodor in malignant fungating wounds are expected to be in late 2026 subject to FDA approving the Phase 3 trial protocol. Even if the primary endpoints of such trials are met and VT-1953 or VT-1908 demonstrate meaningful results in such therapeutic scores, there is no guarantee that such results will lead to the market acceptance or commercial success of VT-1953 and VT-1908, if approved. Even if VT-1953 successfully concludes Phase 3 and other required development work, and thereafter receives marketing approval, it may not achieve commercial success. If we do not accurately evaluate the commercial potential or target market for VT-1953 and VT-1908, we may relinquish valuable

rights to VT-1953 and/ or VT-1908 through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. We may make incorrect determinations regarding the viability or market potential of VT-1953 or VT-1908 or misread trends in our industry.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital for general corporate purposes, in the future we may offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings.

We may in the future license additional assets, which may require us to expend additional resources and raise additional capital.

We are actively engaged in evaluating additional assets for in-licensing or partnership and may execute additional transactions to add to our pipeline. We have not yet entered into any agreements for any such in-licensing or partnership transactions. Furthermore, there is no guarantee that we will successfully enter into any such agreements. In the event that we do enter into any additional license or partnership agreements, it is likely that we will need to expend additional resources and raise additional capital after the closing of the Merger. The ability to do so, to some extent, is subject to market, economic, financial, competitive, legislative and regulatory factors as well as other factors that are beyond our control. There can be no assurance that our business will generate cash flow from operations, or that additional capital will be available to us, in amounts sufficient to enable us to fund our liquidity needs.

Risks Related to Vyome's Product Development

We have never successfully completed the regulatory approval process for the Vyome Assets, and we may be unable to do so for any product candidates we acquire or develop.

- We have not yet demonstrated our ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. If we are required to conduct additional preclinical studies or clinical trials of the Vyome Assets beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of the Vyome Assets or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:
- be delayed in obtaining regulatory approval from the FDA, EMA or other regulatory authorities for the Vyome Assets;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements from the FDA, EMA or other regulatory authorities; or
- experience having the product removed from the market after obtaining regulatory approval.

We are substantially dependent on the success of VT-1953 and VT-1908, and our anticipated clinical trials of VT-1953 and VT-1908 may not be successful.

Our future success is substantially dependent on our ability to successfully develop VT-1953 and VT-1908 for future marketing approval, and then successful commercialization. We are investing a majority of our efforts and financial resources into the research and development of VT-1953 and VT-1908. We plan to commence a Phase 3 trial for VT-1953 in the first half of 2025 subject to approval of protocol by

FDA. We expect to have primary-end point readouts in late 2026. The Company is yet to have the meeting with FDA on Phase 3 trial protocol and also for obtaining orphan drug designation. We also plan to initiate IND enabling studies followed by Phases 1 and 2 commencing in the last quarter of 2025 for VT-1908.

VT-1953 and VT-1908 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote VT-1953 and VT-1908 before we receive marketing approval from the FDA, EMA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of VT-1953 and VT-1908 will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any third parties with whom we choose to collaborate in the future. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of VT-1953 and VT-1908, even if approved. If we are not successful in commercializing VT-1953 and VT-1908, or are significantly delayed in doing so, our business will be materially harmed.

We may find it difficult to enroll patients in our clinical trials for Vyome Assets. If we experience delays or difficulties in the enrollment of patients in clinical trials, our successful completion of clinical trials or receipt of marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for the Vyome Assets if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Patient enrollment may be affected by various factors, including if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as the Vyome Assets, and patients instead enroll in such clinical trials. Our inability to enroll a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs or may require us to abandon one or more clinical trials altogether. In addition, disruptions that can be caused by any pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

The results of preclinical testing and early clinical trials of the Vyome Assets may not be predictive of the success of our later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or other comparable foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that the Vyome Assets are safe and effective before we can seek marketing approvals for commercial sale.

Demonstrations of efficacy or an acceptable safety profile in prior preclinical studies of the Vyome Assets do not mean that future clinical trials will yield the same results, and the translational work that we need to conduct may fail. For instance, we do not know whether the Vyome Assets will perform in future preclinical or clinical trials as the Vyome Assets have performed in preclinical studies and early clinical trials conducted. Vyome Assets may fail to demonstrate in later-stage clinical trials sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other comparable foreign regulatory authorities despite having progressed through preclinical studies and earlier stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety or efficacy results in preclinical studies or earlier-stage trials, which could prevent us from conducting the clinical trials we currently anticipate. There is no guarantee that the FDA, EMA, and other comparable foreign regulatory authorities will consider the data obtained from prior trials sufficient to allow us to initiate the planned trials for Vyome products within the timelines we anticipate, or at all. Even if we are able to initiate our planned clinical trial on schedule, there is no guarantee that we will be able to complete such trial on the timelines we anticipate or that such trial will produce positive results. Any limitation on our ability to conduct clinical trials could delay or prevent regulatory approval or limit the size of the patient population that can be treated by the Vyome Assets, if approved.

Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results.

Before obtaining marketing approval from regulatory authorities for commercialization of the Vyome Assets, we must complete clinical trials to demonstrate the safety and efficacy of the Vyome Assets in humans and in selected diseases. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any stage. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials, and the utcome of preclinical studies and early-stage clinical trials for a product candidate for a particular indication may not be predictive of the success of preclinical studies and early-stage clinical trials for the same product candidate for a different indication. In particular, we plan to initiate a Phase 3 trial evaluating VT-1953 in patients for treating malodor in malignant fungating wounds subject to protocol is approved by FDA. If these Phase 3 trials are successful, we could potentially file a new drug application with the FDA. The above Phase 3 trial and next steps are likely to require additional funding beyond the Concurrent Financing. Although data generated till now on VT-1953 in patients with malignant fungating wounds may not yield similar results. If a Phase 3 study is conducted for VT-1953 in patients with malignant fungating wounds the outcome may be different than desired outcome or outcome based on any earlier data. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an investigational new drug application ("IND") or similar application for any of Vyome's products will result in the FDA, EMA, or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required institutional review board ("IRB") approval at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of the Vyome Assets for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements ("GCPs") or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger- scale facilities operated by a contract manufacturing organization ("CMO") and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us. In addition, disruptions caused by any pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the Vyome Assets, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of the Vyome Assets beyond those

that we currently contemplate, if we are unable to successfully complete clinical trials of the Vyome Assets, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

Preliminary, interim data from our clinical trials that we announce or publish may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We might also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the Vyome Assets and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, the Vyome Assets may be harmed, which could harm our business, operating results, prospects or financial condition.

We may develop the Vyome Assets in combination with other therapies, which exposes us to additional risks related to other agents or active pharmaceutical or biological ingredients used in combination with the Vyome Assets.

In the future, we may develop the Vyome Assets to be used with one or more currently approved other therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other regulatory authorities could revoke approval of the therapy used in combination with the Vyome Assets or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

If the FDA or other regulatory authorities revoke their approval of these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

We may also evaluate the Vyome Assets and other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or other regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to the Vyome Assets currently in development and clinical trials, including the potential for serious adverse effects, delays in their clinical trials and lack of FDA approval.

VT-1953 and VT-1908 may have a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit its commercial potential.

If VT-1953 and VT-1908 is associated with undesirable side effects or has unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or INDs,

we may need to interrupt, delay or abandon VT-1953 and VT-1908 development or limit development to more narrow uses or subpopulations in which such potential undesirable side effects or other characteristics (including but not limited, to local safety at the site of application, and systemic side effects based on the levels systemic drug concentrations and any other unknown adverse events) may be less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of VT-1953 and VT-1908, and may adversely affect our business, financial condition and prospects significantly.

Additionally, after VT-1953 or VT-1908 may receive marketing approval, we or others may later identify undesirable side effects or adverse events caused by VT-1953 or VT-1908. In such cases, regulatory authorities may suspend, limit or withdraw approvals of VT-1953 or VT-1908 or seek an injunction against its manufacture or distribution, require additional warnings on the label, including "boxed" warnings, or issue safety alerts, require press releases or other communications containing warnings or other safety information about VT-1953 or VT-1908, require us to change the way VT-1953 or VT-1908 is administered or conduct additional clinical trials or post-approval studies, require us to create a risk evaluation and mitigation strategy ("REMS") which could include a medication guide outlining the risks of such side effects for distribution to patients or impose fines, injunctions or criminal penalties. We could also be sued and held liable for harm caused to patients, and our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of VT-1953 or VT-1908, if approved, and could seriously harm our business. In addition, approval policies, regulations, or the type and amount of preclinical or clinical data necessary to gain approval may change during the course of clinical development of VT-1953 and VT-1908 and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that Vyome's data is insufficient for approval and require additional preclinical, clinical or other studies.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to obtain adequate product liability insurance.

Our business exposes us to a risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. The medical industry has historically been subject to extensive litigation over product liability claims. Claims may be made by consumers, healthcare providers, third-party strategic collaborators or others selling our products.

Our subsidiary, Vyome Therapeutics Limited, has obtained product liability insurance, which covers the use of our products in our clinical trials and any commercial sales, in an amount we believe is appropriate. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost and on acceptable terms for an adequate coverage amount, or otherwise to protect against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

We may be subject to product liability claims even if it appears that the claimed injury is due to the actions of others. For example, despite label instruction, storing products in higher than ideal temperature conditions and products being exposed to heat and sunlight may cause product deterioration and lead to resulting complaints and liability claims. If personnel/ parties are not properly trained or are negligent, the therapeutic effect of our products may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the negligence of one of our suppliers in supplying us with a defective component that injures a patient could be the basis for a claim against us. A product liability claim, regardless of its merit or eventual outcome, could result in decreased demand for our products; injury to our reputation; diversion of management's attention; withdrawal of clinical trial

participants; significant costs of related litigation; substantial monetary awards to patients; product recalls or market withdrawals; loss of revenue; and the inability to commercialize our products under development.

Risks Related to Vyome's Commercial Operations

We face substantial competition, which may result in others discovering, developing, licensing or commercializing products before or more successfully than we do.

We face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Furthermore, pharmaceutical companies that develop and/or market products for the indications we are pursuing are likely to represent substantial competition. While VT-1953 represents a novel mechanism of action in treating malodor in malignant fungating wounds, all the above mechanisms are also of potential therapeutic use in one or more of the indications we plan to pursue in the Phase 3 program. Similarly, while VT-1908 represents a novel mechanism of action in treating uveitis, all the above mechanisms are also of potential therapeutic use in one or more of the indications we plan to pursue in the later phases. If VT-1953 or VT-1908 do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors and off label products.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize VT-1953 or VT-1908. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than VT-1953-and VT-1908 and these competitors may also be more successful than us in manufacturing and marketing their products.

Furthermore, we also face competition more broadly across the market for existing cost-effective treatments. VT-1953 and VT-1908, if approved, may compete with these existing drug and other therapies but may not be competitive with them in price. We expect that if VT-1953 and VT-1908 is approved, it will be priced at a premium over generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, VT-1953 and VT-1908 will pose challenges.

We have recently undertaken a cost reduction plan and reorganization, and may do so again in the future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits therefrom.

In light of recent macroeconomic conditions, we announced a 2024 cost reduction plan and reorganization to promote the long-term sustainability and scalability of the Company. As part of this plan, we have significantly reduced our workforce. This reduction in force, and any other future reductions, and the attrition that may occur following them, result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. These actions and other additional measures we might take to reduce costs could strain our workforce, divert management attention, yield attrition beyond our intended reduction in force, reduce employee morale, cause us to delay, limit, reduce or eliminate certain development plans or otherwise interfere with our ability to operate and grow our business effectively, each of which could have an adverse impact on our business, operating results and financial condition. We may not complete the current or any cost reduction plan and reorganization on the anticipated timetable, and even if successfully completed, we may not achieve the anticipated cost savings, operating efficiencies or other benefits of such activities.

Public health crises such as pandemics or similar outbreaks have affected and could continue to seriously and adversely affect Vyome's preclinical studies and anticipated clinical trials, business, financial condition and results of operations.

In March 2020, the World Health Organization ("WHO") declared COVID-19 a global pandemic. In response to the COVID-19 pandemic, "shelter in place" orders and other public health guidance measures

were implemented across much of United States and India, including in the locations of Vyome's offices, clinical trial sites, key vendors and partners. Specifically, the COVID-19 pandemic impacted Vyome's ability to raise financing on desirable terms, and also led to reduced sales for Vyome Therapeutics Limited as a result of sales being impacted for therapeutic products across most of the industry. As a result of the COVID-19 pandemic, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, Vyome may in the future experience disruptions that could seriously harm its business. Potential disruptions include but are not limited to: delays or difficulties in enrolling patients in, initiating or expanding our clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from Vyome's clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine; interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed; recommendations by federal, state or local governments, employers and others or interruptions of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical trial endpoints; diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors; interruption or delays in the operations of the FDA, EMA, and comparable foreign regulatory authorities including delays in receiving approval from local regulatory authorities to initiate our planned clinical trials; interruption of, or delays in receiving, supplies of the Vyome Assets due to staffing shortages, raw materials shortages, production slowdowns or stoppages and disruptions in delivery systems; and limitations on employee or other resources that would otherwise be focused on the conduct of Vyome's clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions.

The COVID-19 pandemic or similar outbreaks may also affect the ability of the FDA, EMA, and other regulatory authorities to perform routine functions. If global health concerns prevent the FDA, EMA, or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA, EMA, or other regulatory authorities to timely review and process Vyome's regulatory submissions, which could have a material adverse effect on Vyome's business.

The extent to which the COVID-19 pandemic or similar outbreaks may affect Vyome's clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the duration of the pandemic, new or continued travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States, India and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, India and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to Vyome's clinical trials, business, financial condition and results of operations.

The COVID-19 pandemic or other similar outbreaks may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Our business, operations, financial position and clinical development plans and timelines, and our ability to consummate the Merger, could be materially adversely affected by the ongoing conflicts in various parts of the world.

As a result of the military action commenced in February 2022 by the Russian Federation in Ukraine, and related economic sanctions imposed by certain governments, as well as the ongoing conflicts in the Middle East, our ability to consummate the Merger, and our financial position and operations following the Merger, may be materially and adversely affected. As our ability to continue to operate following the Merger will be dependent on raising debt and equity finance, any adverse impact to those markets as a result of this military action, including due to increased market volatility, decreased availability in third-party financing and/or a deterioration in the terms on which it is available (if at all), could negatively impact our business, operations or financial position. The extent of any potential impact is not yet determinable, however.

Risks Related to Vyome's Business and Operations

We are dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining qualified personnel, including consultants, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain qualified managerial, scientific and medical personnel. We are dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer. If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts. We have relied upon and plan to continue to rely upon third parties, including consultants, to act in management roles for the Company. While we have agreements with such third parties, we do not have the same ability to influence their time commitment to the Company as we would if they were employees. Furthermore, we are dependent on our ability to attract, hire, relocate and retain qualified managerial, scientific and medical personnel from various jurisdictions. Therefore, immigration requirements may have a significant influence on our human resources planning. Immigration applications can take several months or more to be finalized. If we are unable to complete the requisite visa applications, either as a result of changing requirements or otherwise, our ability to successfully implement our business strategy could suffer, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on third parties, including consultants, independent clinical investigators and CROs to conduct and sponsor some of the clinical trials of the Vyome Assets. Any failure by a third party to meet its obligations with respect to the clinical development of the Vyome Assets may delay or impair our ability to obtain regulatory approval for the Vyome Assets.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, academic partners, medical institutions, regulatory affairs consultants and third-party CROs, to conduct our preclinical studies and clinical trials, including in some instances sponsoring such clinical trials, and to engage with regulatory authorities and monitor and manage data for our ongoing preclinical and clinical programs. While we have, or will have, agreements governing the activities of such third parties, we will control only certain aspects of their activities and have limited influence over their actual performance.

Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new contract research organization begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

We remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and other regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our academic partners or CROs or if we or any of our academic partners or CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us, our academic partners or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product

produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for the Vyome Assets. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize the Vyome Assets.

In addition, with respect to investigator-sponsored trials that may be conducted for VT-1953, we do not control the design or conduct of these trials, and it is possible that the FDA or EMA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including the ability to obtain a license to obtain access to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we do not have control over the timing and reporting of the data from investigator-sponsored trials, nor do we own the data from the investigator- sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of the Vyome Assets, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. Additionally, the FDA or EMA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or EMA may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We expect to experience significant growth in the number of our employees and/or number of consultants as well as the scope of our operations, particularly in the areas of drug development, clinical operations, regulatory affairs and, potentially, others. To manage our anticipated future growth, we must continue to implement and develop our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism,

war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage, and the development and commercialization of the Vyome's Assets could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

Vyome generates all of its revenues from one customer, and loss of business from such customer could significantly harm its revenues and business.

Vyome derives its revenues from the sale of products, including royalties related to the sales of such products from one customer, Sun Pharma. Vyome's ability to maintain close relationships with its existing customer will be essential to the growth and profitability of the Combined Company's business. The services we provide to our customers, and the revenues and income from those services, may decline or vary as the type and quantity of products we provide changes over time. In addition, our reliance on any individual customer for all or a significant portion of our revenues may give that customer a certain degree of pricing leverage against us when negotiating contracts and terms of service and require us to accept prices that may be unfavorable to us. In addition, a number of factors other than our performance could cause the loss of or reduction in business or revenues from a customer, and these factors are not predictable. These factors may include organization restructuring, pricing pressure, changes to our development strategy, the supplier switching to another provider or moving production in-house. The loss of this customer, or a significant reduction in sales to such customer, could adversely affect our financial condition and operating results.

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize the Vyome Assets.

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations, even if responsibilities have been outlined in agreements with external partners, such as CROs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to the Vyome Assets. These third parties may also have relationships with

other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize the Vyome Assets.

We intend to rely on third parties to produce and process the Vyome Assets. There can be no assurance that we will successfully negotiate agreements with third-party manufacturers to produce the Vyome Assets on acceptable terms or at all; and furthermore, we may fail to successfully transfer the manufacturing technology to these third-parties. Our business could be adversely affected if the third-party manufacturers are unable to produce the Vyome Assets, fail to provide us with sufficient quantities of the Vyome Assets or fail to do so at acceptable quality levels or prices.

We do not currently own or operate any facility that may be used to produce the Vyome Assets (including any drug substance or finished drug product) and must rely on CMOs to produce them for us.

We have not yet caused the Vyome Assets to be manufactured on a commercial scale and it may not be able to do so for the Vyome Assets, if approved. We do not currently own any cGMP compliant the Vyome Assets and will not be able to conduct any clinical trials until we do. There can be no assurance that we will successfully negotiate agreements with CMOs to produce the Vyome Assets on acceptable terms or at all.

We have not participated in the manufacturing process of, and are completely dependent on, our contract manufacturing partners for manufacture of the Vyome Assets and for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of the Vyome Assets. If our partners do not successfully carry out their contractual duties, meet expected deadlines, or manufacture VT-1953, VT-1908, and VB-1953 in accordance with regulatory requirements, or if there are disagreements between us and our CMO, we will not be able to complete, or may be delayed in completing, the clinical trials required to support approval of the Vyome Assets or the FDA, EMA or other regulatory agencies may refuse to accept our clinical or preclinical data. If the FDA, EMA, or a comparable foreign regulatory authority does not approve these facilities for the manufacture of the Vyome Assets or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market the Vyome Assets, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of the Vyome Assets, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of the Vyome Assets and harm our business and results of operations.

Moreover, if any CMOs on which we will rely are unable to produce the Vyome Assets at all, or fail to manufacture quantities of the Vyome Assets at quality levels necessary to meet our clinical requirements, or regulatory requirements at a scale sufficient to meet anticipated demand, and at a cost that allows us to continue development and to achieve profitability, our business, financial condition and prospects could be materially and adversely affected — including delaying the start of our phase 3 study on the treatment of malodor fungating wounds, which we expect to start in 2025 as well as phase 1 and phase 2 trials for VT-1908. Our business could be similarly affected by business disruptions to our third-party providers with potential impacts on our future revenue and financial condition and our costs and expenses. If any CMOs we contract with are unable to meet our timelines or cost and quantity demands, we may need to find additional CMOs and negotiate new manufacturing agreements. We may also incur substantial fees if we contract with a CMO to access a cell-line and then ultimately decide not to use that cell-line or that CMO for the manufacturing of the Vyome Assets. Each of these risks could delay or prevent the commencement as well as the completion of our clinical trials or the approval of the Vyome Assets by the FDA, including by causing us to have to redo Phase 1 clinical studies, which would result in higher costs and could adversely impact the commercialization of the Vyome Assets.

In addition, some third party CMOs have intellectual property, such as patents and/or know-how with an annual fee and royalty bearing license to its customers that forms part of the manufacturing agreement. This obligation to pay a royalty for manufacturing increases the overall cost of goods and can reduce profitability or reduce the valuation of the product; and we intend to have such an agreement in place.

We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to the Vyome Assets and/or the Company more broadly. Any of these relationships may require us to increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for the Vyome Assets because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view the Vyome Assets as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval. Further, collaborations involving the Vyome Assets are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of the Vyome Assets or may elect not to continue or renew development or commercialization of the Vyome Assets based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as the Merger that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with the Vyome Assets;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly protect our intellectual property or proprietary information or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of the Vyome Assets, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidate; and
- collaborators may own or co-own intellectual property covering the Vyome Assets that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property or may require a license from the collaborator for such intellectual property wholly owned by them in order to commercialize the product candidate.

As a result, if we enter into future collaboration agreements and strategic partnerships or license the Vyome Assets, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or

otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Furthermore, if conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Any delays in entering into future collaborations or strategic partnership agreements related to the Vyome Assets could delay the development and commercialization of the Vyome Assets in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of the Vyome Assets, if any. Social media practices in the biotechnology and biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about the Vyome Assets. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidate or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon completion of the Merger, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We may identify material weaknesses in our internal control over financial reporting in the future or fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of Vyome's consolidated financial statements or cause Vyome to fail to meet its periodic reporting obligations.

As a public company, Vyome Holdings, Inc. which will focus on Vyome's business of advancing the development of its immuno-inflammatory assets and on identifying additional opportunities between the world-class Indian innovation corridor and the U.S. market, will be required to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act and make a formal assessment of the effectiveness of Vyome's internal controls over financial reporting.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will prevent or avoid control deficiencies that could lead to material weaknesses in our internal control over

financial reporting in the future. Our current controls, and any new controls that we develop, may become inadequate because of changes in conditions in our business. Further, deficiencies in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods.

Vyome has not performed a formal evaluation of its internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, nor has it engaged an independent registered public accounting firm to perform an audit of its internal control over financial reporting as of any balance sheet date or for any period reported in its financial statements. Vyome will be required to evaluate and disclose changes made in its internal controls and procedures on a quarterly basis. Failure to comply with the Sarbanes-Oxley Act could potentially subject Vyome to sanctions or investigations by the SEC, the applicable stock exchange or other regulatory authorities, which would require additional financial and management resources. Vyome has begun the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 in the future, but may not be able to complete its evaluation, testing and any required remediation in a timely fashion.

If Vyome fails to maintain an effective system of disclosure controls and internal control over financial reporting, Vyome's ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired, which may adversely affect investor confidence in Vyome and, as a result, the market price of Vyome's common stock.

As a public company, Vyome will be required to comply with the requirements of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, including, among other things, that Vyome maintain effective disclosure controls and procedures and internal control over financial reporting. Vyome continues to develop and refine its disclosure controls and other procedures that are designed to ensure that information Vyome is required to disclose in the reports that Vyome will file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is accumulated and communicated to Vyome's management, including Vyome's principal executive and financial officers.

Vyome must continue to improve its internal control over financial reporting. Vyome will be required to make a formal assessment of the effectiveness of its internal control over financial reporting. To achieve compliance with these requirements within the prescribed time period, Vyome will be engaging in a process to document and evaluate Vyome's internal control over financial reporting, which is both costly and challenging. In this regard, Vyome will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of Vyome's internal control over financial reporting, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that Vyome will not be able to conclude, within the prescribed time period or at all, that Vyome's internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. Moreover, Vyome's testing, or the subsequent testing by Vyome's independent registered public accounting firm, may reveal additional deficiencies in Vyome's internal control over financial reporting that are deemed to be material weaknesses.

Any failure to implement and maintain effective disclosure controls and procedures and internal control over financial reporting, including the identification of one or more material weaknesses, could cause investors to lose confidence in the accuracy and completeness of Vyome's financial statements and reports, which would likely adversely affect the market price of Vyome's common stock. In addition, Vyome could be subject to sanctions or investigations by the stock exchange on which Vyome's common stock is listed, the SEC and other regulatory authorities.

Risks Related to Vyome's Intellectual Property

Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to the Vyome Assets and our technologies and to prevent third parties from infringing on our intellectual property, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain and maintain patent protection for the Vyome Assets and its uses, components, formulations, methods of manufacturing and methods of treatment, as well as our ability to operate without infringing on or violating the proprietary rights of others. We have licensed rights to a composition of matter patent family related to the product. Our intellectual property strategy is, where appropriate, to file new patent applications on inventions, including improvements to existing products/candidates and processes to improve our competitive edge or to improve business opportunities. We continually assess and refine our intellectual property strategy to ensure appropriate protection and rights are secured. Thus, we may be able to file patent applications in the United States and abroad related to our novel discoveries and technologies, for example new uses/methods of treatment, new formulations and improvements to manufacturing methods, that are important to our business, as opportunities arise.

Our strategy requires us to license assets from third parties with suitable protection and to identify and seek patent protection for our inventions, when possible. This process is expensive and time consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions where protection may be commercially advantageous, or we may financially not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information we regard as proprietary. Where possible, we seek to file for patent protection in commercial jurisdictions relevant to the product or technology; however, this is assessed on a case-by-case basis.

Licensing assets from third parties involves technical and scientific due diligence to assess the opportunity, the strength of the intellectual property protection for the asset and the ability to commercialize the asset. This due diligence is usually conducted over a relatively short period of time. It can be difficult to identify all the issues relevant to the assessment. Failure to identify all the relevant issues can impact negatively on the value of the asset.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our future patent applications may not result in patents being issued which protect our technology or drug candidates or which do not effectively prevent others from commercializing competitive technologies and drug candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent. For example, in January 2023, the Opposition Division of the European Patent Office invalidated one of our patents relating to "Topical Oil compositions for the treatment of fungal infections."

The issuance of a patent does not ensure that it is valid or enforceable. Therefore, even if we are issued a patent, it may not be valid or enforceable against third parties. Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by pharmaceutical and biotechnology companies. Thus, any of our patents, including patents that we may rely on to protect our market for approved drugs, may be held invalid or unenforceable by a court of final jurisdiction.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our

issued patents or future patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our future patents in the United States, Europe and in many other jurisdictions cannot be predicted with certainty and, as a result, any future patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our patent applications that we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that prevent marketing of our products or working our own technology. We endeavor to identify early third-party patents and patent applications which may be blocking a product or technology, to minimize this risk. However, relevant documents may be overlooked or missed, which may in turn impact our ability to commercialize the relevant asset.

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions, including the United States, Europe, China and Japan, the basic patent term is 20 years from the earliest filing date of a non-provisional patent application, subject to the payment of renewal fees. Some jurisdictions, including the United States, Europe and Japan, provide for up to an additional five years as a patent term extension for therapeutics products that require marketing approval. The requirements for this supplementary protection are set by the relevant authorities in the given jurisdiction. Products approved before the expiry of the basic patent term may benefit from such a patent term extension. It is our strategy to apply for such supplementary protection, where possible.

In addition to patent protection, statutory provisions in the United States, Europe and other jurisdictions may provide a period of clinical data exclusivity which may be followed by an additional period of market exclusivity to compensate for the time required for regulatory approval of our drug products. Once the relevant criteria are satisfied, the protection applies automatically. The length of protection depends on the jurisdiction and may also depend on the type of therapy.

Third parties may seek to market “similar” versions of our approved products. Alternatively, third parties may seek approval to market their own products, similar or otherwise, competitive with our products. We may not be able to block the commercialization of these products, which may erode our commercial position in the marketplace.

If disputes over intellectual property and other rights that we have licensed, own in the future or co-own in the future prevent or impair our ability to maintain our current licensing or exclusivity arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate. In addition, under certain of our collaboration agreements, our licensors may retain the right of a non-exclusive license to the licensed patents and technology for non-clinical research purposes.

We enjoy only limited geographical protection with respect to our licensed patents and may not be able to protect our intellectual property rights throughout the world.

We may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents worldwide can be prohibitively expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States. All renewal fees required to maintain the patent rights are current.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest US non-provisional filing date. In Europe (and all jurisdictions noted above), the expiration of an invention patent is 20 years from its filing date. For all non-US applications, the PCT filing date is utilized for purposes of calculating the non-US patent expiration dates.

This list of territories has some notable omissions, particularly manufacturing territories such as China, India and Singapore for some of the Vyome Assets.

Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed, for example in countries where we do have patent protection or pending patent applications.

Our future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of VT-1953, VT-1908 and VB-1953 and other Vyome Assets or its intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or the Vyome Assets. Further, even if these patents are granted, they may be difficult to enforce.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office ("USPTO") and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedurals, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. For instance, in the past, Vyome has had to abandon a few patent rights due to its inability to make payments of the required patent fees or annuities within the prescribed timelines. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved.

Issued patents covering one or more of our drug candidates could be found invalid or unenforceable.

Any issued patents that we may license or own covering the Vyome Assets could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO. Patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position with respect to the Vyome Assets for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, enforceability of our patents and/or other intellectual property. Finally, changes in US patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect the Vyome Assets. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market the Vyome Assets under patent protection would be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or

invalidate, our patent rights, allow third parties to commercialize our technology or the Vyome Assets and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize the Vyome Assets. In addition to seeking patents for some of our technology and the Vyome Assets, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while the company undertakes efforts to protect its trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of Vyome shares. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Patent terms may be inadequate to protect our competitive position with respect to the Vyome Assets for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Once patents covering the Vyome Assets have expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new

product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for the Vyome Assets, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. However, a patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when the Vyome Assets receive FDA approval, we expect to apply for patent term extension on patents covering the Vyome Assets, there is no guarantee that the applicable authorities will agree with our assessment of whether such extension should be granted, and even if granted, the length of such extension. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering the Vyome Assets that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (a/k/a the “Purple Book”), a searchable, online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act). We may be unable to obtain patents covering the Vyome Assets that contain one or more claims that satisfy the requirements for listing in the Purple Book. Even if we submit a patent for listing in the Purple Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If is the Vyome Assets are approved and patents covering either of the Vyome Assets are not listed in the Purple Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of either of the Vyome Assets.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect the Vyome Assets.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) could increase the uncertainties and costs surrounding the prosecution of our future owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission

of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent US Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and altered the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future legislation by the US Congress, decisions by the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. For example, in the case Amgen v. Sanofi, the Federal Circuit held broad functional antibody claims invalid for lack of enablement. Similarly, in the case Juno v. Kite, the Federal Circuit held genus claims directed to CAR-T cells invalid for lack of written description for failing to provide disclosure commensurate with the scope of the claims. While we do not believe that any of the patents licensed or owned by us will be found invalid based on these decisions, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market the Vyome Assets.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant third party patents, the scope of said patent claims or the expiration of relevant patents, are complete, accurate or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of the Vyome Assets in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market the Vyome Assets.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering the Vyome Assets or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements

may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable.

Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing the Vyome Assets or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing the Vyome Assets.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and is interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on or violating third party rights. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon the Vyome Assets and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g., patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds and on the market price of the shares of the post-Merger company's common stock.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our patents through procedures created to challenge the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

In addition, if either of the Vyome Assets is found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with

whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain a license for one or both of the Vyome Assets.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may not be able to effectively secure first-tier technologies when competing against other companies or investors.

Our future success may require that we acquire patent rights and know-how to new or complementary technologies. However, we compete with a substantial number of other companies that may also compete for technologies we desire. In addition, many venture capital firms and other institutional investors, as well as other biotechnology companies, invest in companies seeking to commercialize various types of emerging technologies. Many of these companies have greater financial, scientific and commercial resources than us. Therefore, we may not be able to secure the technologies we desire. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and/or technologies.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we may file or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensor) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensor) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;

- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

If approved, the Vyome Assets that are regulated by FDA, EMA and other regulatory authorities may face competition from generics approved through an abbreviated regulatory pathway.

We believe that if either of the Vyome Assets is approved in the United States as a biological product under an NDA and orphan drug designation in certain cases it would qualify for the 3 and 7-year period of exclusivity, respectively. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of the Vyome Assets could have a material adverse impact on our business due to increased competition and pricing pressure.

Risks Related to Government Regulations and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA, and other comparable foreign regulatory authorities are complex, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for the Vyome Assets, we may not be able to commercialize, or may be delayed in commercializing, the Vyome Assets, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals in the United States, European Union ("EU"), and other jurisdictions is complex, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the Vyome Assets involved. We cannot commercialize VT-1953, VT-1908 and VB 1953 in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize VT-1953, VT-1908 and VB 1953 outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of the Vyome Assets, we must demonstrate through complex and expensive preclinical studies and clinical trials that the Vyome Assets are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. Further, the Vyome Assets may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA, EMA, and comparable foreign regulatory authorities have discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Either VT-1953, VT-1908 and VB-1953 could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities that is the Vyome Assets are safe and effective for their proposed indications; the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to the Vyome Assets; we may be unable to demonstrate that the clinical and other benefits of the Vyome Assets outweigh their safety risks; the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of the Vyome Assets may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA, EMA, or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of the Vyome Assets; the FDA, EMA, or

comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Thus, the approval requirements for the Vyome Assets are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predicative of success elsewhere.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, EMA, or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market the Vyome Assets, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve the Vyome Assets for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve the Vyome Assets with a label that does not include the labeling claims necessary or desirable for the successful commercialization of the Vyome Assets. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for the Vyome Assets, we may not be able to commercialize, or may be delayed in commercializing, the Vyome Assets and our ability to generate revenue could be materially impaired.

We will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with the Vyome Assets.

Any regulatory approvals that we may receive for the Vyome Assets will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the Vyome Assets, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. In addition, if the FDA, EMA, or comparable foreign regulatory authorities approve VT-1953, VT-1908 and VB-1953, the Vyome Assets and the activities associated with their respective development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA in the EU and comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices ("cGMPs") and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA, and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discover previously unknown problems with the Vyome Assets, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the Vyome Assets are manufactured, a regulatory authority may impose restrictions on the Vyome Assets, the manufacturing facility or us, including requiring recall or withdrawal of the Vyome Assets from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize the Vyome Assets and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's, EMA's and other regulatory comparable authorities' policies may change and additional government regulations may be enacted that could prevent, limit, delay, increase the cost or risks of obtaining regulatory approval of the Vyome Assets, including if as a result new or more costly or difficult to achieve clinical trial or manufacturing quality requirements are imposed. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain

regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer the Vyome Assets at competitive prices which would seriously harm our business.

Our ability to successfully commercialize the Vyome Assets also will depend in part on the extent to which reimbursement for Vyome Assets and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

The FDA, EMA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If one or both of the Vyome Assets is approved and we are found to have improperly promoted off-label uses of the Vyome Assets, we may become subject to significant liability. If we cannot successfully manage the promotion of the Vyome Assets, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. We expect to adopt a code of conduct following the Closing of the Merger to more closely reflect our operations, but it is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws in USA and India, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute the Vyome Assets, if approved. See the section titled “Description of Vyome’s Business — Government Regulation” for a more detailed description of the laws that may affect our ability to operate.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any of the Vyome Assets for which we obtain regulatory approval. Our future arrangements with third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any of the Vyome Assets for which we obtain regulatory approval.

The size of the potential market for the Vyome Assets is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for the Vyome Assets may be smaller than our estimates.

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of the indications that may be addressable by the Vyome Assets,

which is derived from a variety of sources, including scientific literature and surveys of clinics. Our estimations may prove to be incorrect and the number of potential patients may turn out to be lower than expected.

The total addressable market opportunity for the Vyome Assets will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, the success of competing therapies and product pricing and reimbursement. Even if we obtain significant market share for the Vyome Assets, because the potential target populations could be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act ("ACA"). It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to amend or challenge the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs the U.S. Department of Health and Human Services ("HHS") to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans

for drugs from Canada. On September 25, 2020, the HHS's Centers for Medicare & Medicaid Services ("CMS") stated that drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of the Vyome Assets. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development ("OECD") countries with a similar gross domestic product per capita. However, the MFN rule was immediately challenged in federal courts and on August 6, 2021 CMS announced a proposed rule to rescind it. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. In response to litigation, the Biden administration agreed to delay the effective date of the rule until January 1, 2023. Further, implementation of these changes and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. The effect of these legislative and executive activities on our business model and operations is currently unclear.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We may be subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

Our operations, directly or indirectly through customers, may be subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

We may be unable to predict whether it could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of its operations.

If we fail to comply with environmental, health and safety laws and regulations in the USA, India or where we may have operations in future, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our external partners are subject to complex environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes, and the rehabilitation of contaminated sites. Our operations, including those performed by our external partners, may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we and/or our external partners may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to laws and regulations related to privacy, data protection, information security and consumer protection across different markets where we conduct our business. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to laws and regulations related to, among other things, privacy, data protection, information security and consumer protection across different markets where we conduct our business. Such laws and regulations are constantly evolving and changing and are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an adverse effect on our business, operating results and financial operations. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the potential or actual misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third party, could adversely affect our business, financial condition, and results of operations, including but not limited to investigation costs, material fines and penalties, compensatory, special, punitive, and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services, and/or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive relief.

European data collection is also governed by restrictive regulations governing the use, processing and cross-border transfer of personal information. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation ("GDPR"), which imposes strict requirements for processing the personal data of individuals within the European Economic Area (the "EEA"). The GDPR is directly applicable in each EU member state and is extended to the EEA. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to

processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR implements more stringent operational requirements than its predecessor legislation. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. For example, the GDPR applies extraterritorially, requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for collecting and processing personal data (including data from clinical trials), requires the appointment of data protection officers, such as when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, including far reaching information rights and the right to erasure, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training, and data audit. The GDPR provides that EU member states and EEA countries may establish their own laws and regulations that go beyond the GDPR in certain areas, such as regarding the mandatory appointment of data protection officers or further limiting the processing of personal data, including genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and the United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union ("CJEU"). While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. After Brexit the United Kingdom is also a third country from an EU perspective, but the EU Commission adopted adequacy decisions for the United Kingdom on June 28, 2021 largely permitting the free flow of data from the EU to the United Kingdom. However, for the first time, the adequacy decisions include a so-called "sunset clause" and, therefore, will automatically expire four years after their entry into force.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage, and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We do not have a compliance program in place consistent with Federal agencies' guidance's on corporate compliance programs.

We have not established a formal compliance function with the independence and resources that Federal regulators or other regulators where its subsidiaries operate would expect of corporate compliance programs. Accordingly, policies and procedures have yet to be developed and compliance training, auditing, and monitoring activities have not occurred. We have not established a Chief Compliance Officer nor have we created a compliance hotline for employees to report complaints or potential compliance violations. Accordingly, risks associated with the aforementioned regulatory scheme may arise undetected and unmitigated by corporate leadership. Furthermore, any potential enforcement action for regulatory violations

might result in compliance obligations in addition to fines, penalties, or administrative actions (e.g., U.S. Department of Justice monitorships or U.S. Department of Health and Human Services, Office of Inspector General Corporate Integrity Agreements).

Our business is subject to certain laws and regulations in the jurisdictions in which it operates, many of which are currently evolving, and the risk of unfavorable interpretations or failure to comply with such laws and regulations could harm our business, financial condition and results of operations.

We are subject to differing, and sometimes conflicting, laws and regulations in the various jurisdictions in which we operate our business, which are evolving and may change from time to time, which may give rise to inconsistent or ambiguous interpretations among local, regional, or national laws or regulations applicable to our business. Compliance with laws and regulations of different jurisdictions imposing varying standards and requirements is burdensome for businesses like ours, imposes added cost, increases potential liability to our business, and makes it difficult to realize business efficiencies and economies of scale.

Relative to India, the operation of our business is informed by a regulatory framework which includes but is not limited to, the laws of Delhi Pollution Control Board, labor laws, corporate laws, income tax laws, laws applicable to taxation of goods and service tax laws, foreign exchange control laws in India, which informs how we operate and the ways in which we promote our business. However, there can be no assurance that our interpretation of relevant Indian laws and regulations, including the Foreign Exchange Management Act, 1999, is complete or correct, or that authorities in India will interpret this or other applicable regulations the same way that we do. In the event that the applicable laws and regulations are interpreted in a manner unfavorable to us, we could become the subject of investigations and could potentially face fines, duties, judgments or other negative consequences, which could materially adversely affect our business and results of operations. Additionally, as our business continues to grow and evolve, laws and regulations will be amended to address the evolution of our business, resulting in new and unpredictable legal and regulatory obligations in emerging markets. It may be difficult for us to comply with the new laws and regulations that will be developed to address changes in our industry and business, and we cannot guarantee that we will be able to comply with such new laws and regulations. If our current or future business models are determined to be noncompliant with the national, regional, and local laws and regulations, we may be required to make costly adjustments to our business model, which could result in negative consequences, many of which may be outside of our control and impossible to predict.

In addition, we are subject to laws and regulations governing other aspects of our business practices, including laws and regulations relating to taxation, online payments, automobile-related liability, consumer privacy and data protection, pricing, content, advertising, discrimination, consumer protection, protection of intellectual property rights, distribution, messaging, mobile communications, environmental matters, labor and employment matters, claims management, electronic contracts, communications, Internet access, securities and public disclosure, corruption and anti-bribery, and unfair commercial practices. In addition, climate change and greater emphasis on sustainability could lead to regulatory efforts to address the carbon impact of transportation and mobility, which could have a negative impact on our business.

In addition, the jurisdictions in which we have business operations may in the future enact new laws and regulations relating to emissions and other environmental matters our operations, the peer-to-peer car sharing industry generally, and the operation of our business. The interpretation and enforcement of such laws may involve significant uncertainties. New laws and regulations that affect our existing and proposed future businesses may also be applied retroactively in ways that we cannot predict with certainty.

We cannot predict the effect that the interpretation of existing or new laws or regulations may have on our business. Any of the foregoing or similar occurrences or developments could significantly disrupt our business operations and restrict us from conducting a substantial portion of our business operations in these jurisdictions, which could adversely affect our business, financial condition or operating results.

Political changes in the Government of India could delay or affect the further liberalization of the Indian economy and materially and adversely affect economic conditions in India, generally, and our business, in particular.

Our business could be significantly influenced by economic policies adopted by the government of India. Since 1991, successive governments have pursued policies of economic liberalization and financial

sector reforms. The government has at various times announced its general intention to continue India's current economic and financial liberalization and deregulation policies. However, protests against such policies, which have occurred in the past, could slow the pace of liberalization and deregulation. The rate of economic liberalization could change, and specific laws and policies affecting foreign investment, currency exchange rates and other matters affecting investment in India could change as well. While we expect any new government to continue the liberalization of India's economic and financial sectors and deregulation policies, there can be no assurance that such policies will be continued.

The government of India has traditionally exercised and continues to exercise influence over many aspects of the economy. Our business may be affected by interest rates, changes in policy, taxation, social and civil unrest and other political, economic or other developments in or affecting India.

A change in the government's economic liberalization and deregulation policies could disrupt business and economic conditions in India generally, and specifically our business and operations, as substantially all of our business and operations are located in India. This could have a material adverse effect on our business, prospects, financial condition and results of operations.

Vyome's Indian subsidiary may not be in compliance with laws applicable to it, and it may face penalties and fines imposed by the Indian government.

Vyome has not retained local counsel to assess whether its subsidiary, Vyome Therapeutics Limited, is in compliance with applicable local law. There can be no assurance that Vyome will be able to initially meet such requirements or maintain compliance with the laws and regulations of each foreign country in which its subsidiary operates. As a result, Vyome and its subsidiary, Vyome Therapeutics Limited, may be subject to adverse legal consequences, including but not limited to penalties and fines, which could adversely affect the business, financial condition or results of operations of Vyome.

LEGAL MATTERS

The validity of the shares of our common stock being offered by this prospectus will been passed upon for us by Fox Rothschild LLP, Minneapolis, Minnesota. The Placement Agent is being represented by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements of ReShape Lifesciences Inc. as of December 31, 2023 and 2022 and for each of the years in the two-year period ended December 31, 2023 have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon (which report expresses an unqualified opinion and includes an explanatory paragraph relating to substantial doubt about ReShape Lifesciences Inc.'s ability to continue as a going concern), and included in this Prospectus and Registration Statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

The financial statements of Vyome Therapeutics, Inc. as of and for the years ended December 31, 2023 and 2022 included in this prospectus have been audited by Kreit & Chiu CPA LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph relating to substantial doubt about Vyome Therapeutics, Inc.'s ability to continue as a going concern). Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing. The office of Kreit & Chiu CPA LLP is located at 733 Third Avenue, Floor 16, #1014 New York, NY 10017, the United States.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the distribution of the securities offered under this prospectus. The registration statement, including the attached exhibits and schedules, contains additional relevant information about us and the securities. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC.

You may also obtain the documents that we file electronically on the SEC's website at *www.sec.gov* or on our website at *www.reshapelifesciences.com*. Information contained on our website is not incorporated by reference herein and does not constitute part of this prospectus.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITY

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the provisions described above, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of ReShape Lifesciences Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ReShape Lifesciences Inc. and its subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows. The Company currently does not generate revenue sufficient to offset operating costs and anticipates such shortfalls to continue. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Going Concern

As described in Note 3 to the financial statements, the Company disclosed certain adverse conditions that raises substantial doubt about the Company's ability to continue as a going concern for a period of at least one year from the date of issuance of the financial statements. The Company further disclosed certain plans identified by management, which involve the use of significant judgment, planned to mitigate the conditions that raise substantial doubt about the Company's ability to continue as a going concern.

We identified the Company's assessment of its liquidity and management's plans to continue as a going concern as a critical audit matter because of the significant assumptions management made in determining the reasonableness of management's cash flow forecast for a period of one year from the date of issuance of the financial statements. Auditing management's assumptions involved a high degree of auditor judgment and an increase in audit effort.

Our audit procedures related to the Company's liquidity and management's plans included the following, among others:

- We obtained management's going concern assessment and evaluated the reasonableness of the likelihood that management could implement its plans and how the implementation of those plans impacted the identified adverse conditions.
- We evaluated the reasonableness of management's cash flow forecast by performing the following procedures, among others:
  - We compared management's projected cash flows to subsequent event activity.
  - We evaluated the reasonableness of forecasted revenues and gross profits assumptions by comparing to internal communications to the board of directors, to historical results and to recent trends.
  - We evaluated the reasonableness of the forecasted nature, amount and timing of operating expenditure reductions and trends over recent history.
- We evaluated the adequacy of the disclosures included in the financial statements regarding management's plan.

/s/ RSM US LLP

We served as the Company's auditor from 2022 to 2024.

Irvine, California
April 1, 2024, except for the effect of the reverse stock split described in Note 1, as to which the date is October 1, 2024.

RESHAPE LIFESCIENCES INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,459	$ 3,855
Restricted cash	100	100
Accounts and other receivables (net of allowance for doubtful accounts of $804 and $410 respectively)	1,659	2,180
Inventory	3,741	3,611
Prepaid expenses and other current assets	337	165
Total current assets	10,296	9,911
Property and equipment, net	60	698
Operating lease right-of-use assets	250	171
Deferred tax asset, net	28	56
Other intangible assets, net	—	260
Other assets	29	46
Total assets	$ 10,663	$ 11,142
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,689	$ 1,926
Accrued and other liabilities	1,814	5,040
Warranty liability, current	163	344
Operating lease liabilities, current	111	171
Total current liabilities	3,777	7,481
Operating lease liabilities, noncurrent	151	—
Common stock warrant liability	72	—
Total liabilities	4,000	7,481
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized:		
Series C convertible preferred stock, $0.001 par value; 95,388 shares issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized at December 31, 2023 and December 31, 2022; 404,437 and 8,955 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	642,325	627,936
Accumulated deficit	(635,574)	(624,187)
Accumulated other comprehensive loss	(88)	(88)
Total stockholders' equity	6,663	3,661
Total liabilities and stockholders' equity	$ 10,663	$ 11,142

See accompanying notes to consolidated financial statements.

RESHAPE LIFESCIENCES INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Revenue	$ 8,678	$ 11,240
Cost of revenue	3,130	4,438
Gross profit	5,548	6,802
Operating expenses:		
Sales and marketing	7,548	14,093
General and administrative	10,324	17,250
Research and development	2,315	2,537
Impairment of long-lived assets	777	18,744
(Gain) loss on disposal of assets, net	(33)	529
Total operating expenses	20,931	53,153
Operating loss	(15,383)	(46,351)
Other expense (income), net:		
Interest (income) expense, net	(26)	113
Gain on changes in fair value of liability warrants	(3,878)	—
(Gain) loss on foreign currency exchange, net	(22)	141
Other	(122)	(11)
Loss before income tax provision	(11,335)	(46,594)
Income tax expense (benefit)	52	(380)
Net loss	$ (11,387)	$ (46,214)
Net loss per share – basic and diluted:		
Net loss per share – basic and diluted	(110.87)	(6,315.92)
Shares used to compute basic and diluted net loss per share	102,707	7,317

See accompanying notes to consolidated financial statements.

RESHAPE LIFESCIENCES INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended December 31,	
	2023	2022
Net loss	$(11,387)	$(46,214)
Foreign currency translation adjustments	—	4
Other comprehensive income, net of tax	—	4
Comprehensive loss	$(11,387)	$(46,210)

See accompanying notes to consolidated financial statements.

RESHAPE LIFESCIENCES INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share amounts)

	Series C Convertible Preferred Stock		Series D Mirroring Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance December 31, 2021 (As Restated)	95,388	$ —	—	$ —	6,149	$ —	$622,399	$(577,973)	$(92)	$ 44,334
Net loss	—	—	—	—	—	—	—	(46,214)	—	(46,214)
Other comprehensive income, net of tax	—	—	—	—	—	—	—	—	4	4
Series D Mirroring preferred stock issued	—	—	2,500	—	—	—	—	—	—	—
Series D Mirroring preferred stock canceled	—	—	(2,500)	—	—	—	—	—	—	—
Stock-based compensation expense, net	—	—	—	—	—	—	2,087	—	—	2,087
Cancellation of common stock	—	—	—	—	(346)	—	—	—	—	—
Common stock purchased	—	—	—	—	826	—	639	—	—	639
Issuance of stock from RSUs	—	—	—	—	369	—	—	—	—	—
Issuance of stock for bonuses	—	—	—	—	497	—	318	—	—	318
Institutional exercise of warrants	—	—	—	—	1,460	—	2,493	—	—	2,493
Balance December 31, 2022	95,388	$ —	—	$ —	8,955	$ —	$627,936	$(624,187)	$(88)	$ 3,661
Net loss	—	—	—	—	—	—	—	(11,387)	—	(11,387)
Other comprehensive income, net of tax	—	—	—	—	—	—	—	—	—	—
Issuance of common stock pursuant to reverse stock split	—	—	—	—	318	—	—	—	—	—
Stock-based compensation expense, net	—	—	—	—	—	—	766	—	—	766
Common stock purchased	—	—	—	—	55,973	—	10,140	—	—	10,140
Equity issuance costs	—	—	—	—	—	—	(653)			(653)
Issuance of stock from RSUs	—	—			44	—	—	—	—	—
Institutional exercise of warrants	—	—	—	—	339,147	—	4,136	—	—	4,136
Balance December 31, 2023	95,388	$ —	—	$ —	404,437	$ —	$642,325	$(635,574)	$(88)	$ 6,663

See accompanying notes to consolidated financial statements.

RESHAPE LIFESCIENCES INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$(11,387)	$(46,214)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	121	330
Amortization of intangible assets	33	1,823
Impairment of long-lived assets	777	18,744
(Gain) loss on disposal of assets, net	(33)	529
Stock-based compensation	766	2,087
Bad debt expense	395	(43)
Provision for inventory excess and obsolescence	335	579
Deferred income tax	28	(423)
Gain on changes in fair value of liability warrants	(3,878)	—
Other noncash items	17	(23)
Change in operating assets and liabilities:		
Accounts and other receivables	125	678
Inventory	(465)	(1,187)
Prepaid expenses and other current assets	(172)	1,141
Accounts payable and accrued liabilities	(3,457)	448
Warranty liability	(182)	(371)
Other	17	—
Net cash used in operating activities	(16,960)	(21,902)
Cash flows from investing activities:		
Capital expenditures	(43)	(131)
Proceeds from sale of capital assets	33	39
Cash used in investing activities:	(10)	(92)
Cash flows from financing activities:		
Proceeds from sale and issuance of securities, net	13,438	639
Proceeds from warrants exercised	4,136	2,491
Net cash provided by financing activities	17,574	3,130
Effect of currency exchange rate changes on cash and cash equivalents	—	4
Net change in cash, cash equivalents and restricted cash	604	(18,860)
Cash, cash equivalents and restricted cash at beginning of period	3,955	22,815
Cash, cash equivalents and restricted cash at end of period	$ 4,559	$ 3,955
Supplemental disclosure:		
Cash paid for income taxes	$ 10	$ 5
Cash paid for interest	—	—
Noncash investing and financing activities:		
Capital expenditures accruals	$ —	$ 6

See accompanying notes to consolidated financial statements.

RESHAPE LIFESCIENCES INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Description of the Business and Risks and Uncertainties

Description of Business

We were incorporated under the laws of Delaware on January 2, 2008. On June 15, 2021, we completed a merger with ReShape Lifesciences Inc. Pursuant to the Merger Agreement, a wholly owned subsidiary of Obalon merged with and into ReShape, with ReShape surviving the merger as a wholly owned subsidiary of Obalon. As a result of the merger, Obalon, the parent company, was renamed "ReShape Lifesciences Inc." and ReShape was named ReShape Weightloss Inc. ReShape Lifesciences' shares of common stock trade on the Nasdaq under the symbol RSLS.

ReShape Medical (formerly ReShape Lifesciences Inc.) was incorporated in the state of Minnesota in December 2002 and reincorporated in the state of Delaware in July 2004. In 2017, the Company changed its name from EnteroMedics Inc. to ReShape Lifesciences Inc.

The Company is headquartered in Irvine, California. The Company is a developer of minimally invasive medical devices that advance bariatric surgery to treat obesity and metabolic diseases. The Company's current portfolio consists of the Lap-Band® Adjustable Gastric Banding System, the Obalon Balloon System, the first and only swallowable gas filled balloon system, and the Diabetes Bloc-Stim Neuromodulation, a technology under development as a new treatment for type 2 diabetes mellitus. The Company sells the Lap-Band worldwide and is managed in the following geographical regions: United States, Australia, Europe and the rest of world. Refer to Note 11 for additional information about operating segments.

Reverse Stock Split

On September 23, 2024, at the commencement of trading, the Company effected a 1-for-58 reverse stock split. Accordingly, all share and per share amounts for the periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split. No fractional shares were issued in connection with the reverse stock split.

Risks and Uncertainties

The Company continues to devote significant resources to developing its product technology, commercialization activities and raising capital. These activities are subject to significant risks and uncertainties, including the ability to obtain additional financing, and there can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. If adequate funds are not available, the Company may have to further reduce its cost structure until financing is obtained and/or delay development, or commercialization of products, or license to third parties the rights to commercialize products, or technologies that the Company would otherwise seek to commercialize. Refer to Note 3 for additional information about the Company's liquidity, going concern and management's plans.

The medical device industry is characterized by frequent and extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often difficult to predict, and the outcome may be uncertain until the court has entered final judgment and all appeals are exhausted. The Company's competitors may assert that its products or the use of the Company's products are covered by U.S. or foreign patents held by them. Refer to Note 14 for additional information about contingencies and litigation matters.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP").

Reverse Stock Splits

On December 23, 2022, at the commencement of trading, the Company effected a 1-for-50 reverse stock split. Accordingly, all share and per share amounts for the periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split. No fractional shares were issued in connection with the reverse stock split.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers highly liquid investments generally with maturities of 90 days or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. The Company's cash equivalents are primarily in money market funds and certificates of deposit. The Company deposits its cash and cash equivalents in high-quality credit institutions.

Restricted Cash

Restricted cash represents $100 thousands at both December 31, 2023 and 2022, related to a collateral money market account maintained by the Company as collateral in connection with corporate credit cards with Silicon Valley Bank.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets to the same total reported in the consolidated statements of cash flows (in thousands):

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$4,459	$3,855
Restricted cash	100	100
Total cash, cash equivalents, and restricted cash in the consolidated statement of cash flows	$4,559	$3,955

Accounts Receivable

The majority of the Company's accounts receivable arise from direct product sales and sales of products under consignment arrangements, and have payment terms that generally require payment within 30 to 90 days. The Company provides reserves against accounts receivable for estimated losses that may result from a customer's inability to pay based on customer-specific analysis and general matters such as current assessments of past due balances, economic conditions and forecasts, and historical credit loss activity. Amounts determined to be uncollectible are charged or written-off against the reserve. Additionally, under the current expected credit loss model, we utilize historical loss rates based on number of days past due, adjusted to reflect current economic conditions and forecasts of future economic conditions.

Inventory

The Company accounts for inventory at the lower of cost or net realizable value, where net realizable value is based on market prices less costs to sell. The Company establishes inventory reserves for obsolescence

based upon specific identification of expired or unusable units with a corresponding provision included in cost of revenue. The allowance for excess and slow-moving inventory was $1.0 million at both December 31, 2023 and 2022.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over their estimated useful lives of five to seven years for furniture and equipment and three to five years for computer hardware and software. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Upon retirement or sale, the cost and related accumulated depreciation or amortization are removed from the Consolidated Balance Sheets and the resulting gain or loss is reflected in the Consolidated Statements of Operations. Repairs and maintenance are expensed as incurred.

Goodwill and Other Long-Lived Assets

Goodwill represents the excess of the cost of an acquired business over the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed in a business combination.

Indefinite-lived intangible assets relate to in-process research and development ("IPR&D") acquired in business combinations. The estimated fair values of IPR&D projects acquired in a business combination which have not reached technological feasibility are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the projects. In accordance with guidance within FASB ASC 350 "Intangibles — Goodwill and Other," goodwill and identifiable intangible assets with indefinite lives are not subject to amortization but must be evaluated for impairment.

Finite-lived intangible assets primarily consist of developed technology and trademarks/tradenames and were being amortized on a straight-line basis over their estimated useful lives. During 2023, the Company fully impaired the finite-lived intangible assets, see Note 6 and Note 7, for further details.

We evaluate long-lived assets, including finite-lived intangible assets, for impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset group may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value or estimates of future discounted cash flows. The Company recorded an impairment to developed technology and IPR&D intangible assets for both the years ended December 31, 2023 and 2022, for further details see Note 6 and Note 7.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the consolidated statements of operations.

Foreign Currency

When the local currency of the Company's foreign subsidiaries is the functional currency, all assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted-average exchange rate prevailing during the period. The effects of foreign currency translation adjustments for these subsidiaries are deferred and reported in stockholders' equity as a component of Accumulated Other Comprehensive Loss. The effects of

foreign currency transactions denominated in a currency other than an entity's functional currency are included in Gain on foreign currency exchange in the Consolidated Statements of Operations. The Company does not hedge foreign currency translation risk in the net assets and income it reports from these sources.

Revenue Recognition

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Product sales consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes product revenue when the following events have occurred: (a) the Company has transferred physical possession of the products, (b) the Company has a present right to payment, (c) the customer has legal title to the products, and (d) the customer bears significant risks and rewards of ownership of the products.

For the Company's Lap-Band product, these criteria are met under the agreements with most customers upon product shipment. This includes sales to distributors, who sell the products to their customers, take title to the products and assume all risks of ownership at the time of shipment. Distributors are obligated to pay within specified terms regardless of when, if ever, they sell the products.

Taxes collected from customers and remitted to governmental authorities are accounted for on a net basis. Accordingly, such amounts are excluded from revenues. Amounts billed to customers related to shipping and handling are included in revenues. Shipping and handling costs related to revenue producing activities are included in cost of sales.

Variable Consideration

The Company records revenue from customers in an amount that reflects the transaction price it expects to be entitled to after transferring control of the goods. Customers and distributors of the Lap-Band product generally have the right to return or exchange products purchased for up to thirty days from the date of product shipment contingent upon a 10% restocking fee. Any such return or exchange of Lap-Band products will be recorded as a reduction of revenue in the period incurred.

Certain Lap-Band customers may receive volume rebates or discounts. Discounts are treated as a reduction in sales price and therefore corresponding revenue at the point of sale. Any volume rebates offered would be estimated and reserved as a reduction in revenue.

Warranty

The Company generally provides warranties against defects in materials and workmanship, and provides replacements at no charge to the customer, as long as the customer has notified the Company within 30 days of delivery and returns such products in accordance with the Company's instructions. As they are considered assurance-type warranties, the Company does not account for them as separate performance obligations. Warranty reserve requirements are based on a specific assessment of the products sold with warranties where a customer asserts a claim for warranty or a product defect.

For the vBloc product line, the Company has a 5-year warranty on all implantable parts. vBloc sales began in 2015 and ended in 2018, so this warranty period went through 2023.

Cost of Goods Sold

The Company expenses to cost of goods sold, direct and indirect inventory costs as sold. Additionally, the Company expenses to costs of goods sold, various indirect costs such as warehousing finished goods, shipping costs of sales to customers, non-production salaries and consulting costs relating to inventory, and portions of salaries that are not allocatable to operating expenses.

Advertising Cost

Advertising costs are expensed as incurred and totaled $2.2 million and $6.8 million for the years ended December 31, 2023 and 2022, respectively.

Stock-Based Compensation

The Company applies ASC 718 Compensation — Stock Compensation and accordingly records compensation expense for stock options over the vesting or service period using the fair value on the date of grant, as calculated by the Company using the Black-Scholes model. The Company's stock-based compensation plans are more fully described in Note 12.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, including the pre-funded warrants, see Note 10, that were reclassified from warrant liability to equity as a result of the reverse stock split. Diluted net loss per share is based on the weighted-average common shares outstanding during the period plus dilutive potential common shares calculated using the treasury stock method. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share. For purposes of basic and diluted per share computations, loss from continuing operations and net loss are reduced by the down round adjustments for convertible preferred stock and warrants.

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	December 31,	
	2023	2022
Stock options	216	370
Unvested restricted stock units	25	79
Convertible preferred stock	10	10
Warrants	268,937	3,336

Concentration of Credit Risk, Interest Rate Risk and Foreign Currency Exchange Rate

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents, restricted cash and trade accounts receivable. Cash and cash equivalents are primarily deposited in demand and money market accounts. At times, such deposits may be in excess of insured limits. Investments in money market funds are not considered to be bank deposits and are not insured or guaranteed by the federal deposit insurance company or other government agency. These money market funds seek to preserve the value of the investment at $1.00 per share; however, it is possible to lose money investing in these funds. The Company has not experienced any losses on its deposits of cash and cash equivalents. To minimize the risk associated with trade accounts receivable, management maintains relationships with the Company's customers that allow management to monitor current changes in business operations so the Company can respond as needed.

Substantially all of the Company's revenue is denominated in U.S. dollars. Only a small portion of revenue and expenses are denominated in foreign currencies, principally the Australian dollar and Euro for 2023 and 2022. The Company has not entered into any hedging contracts. Future fluctuations in the value of the U.S. dollar may affect the price competitiveness of the Company's products outside the U.S.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (referred to as an "exit price"). Fair value of an asset or liability considers assumptions that market participants would use in pricing the asset or liability, including consideration of non-performance risk.

Assets and liabilities are categorized into a three-level fair value hierarchy based on valuation inputs used to determine fair value.

Level 1 inputs are quoted prices in active markets for identical assets or liabilities.

Level 2 inputs are observable, either directly or indirectly.

Level 3 inputs are unobservable due to little or no corroborating market data.

The carrying amounts of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable and certain accrued and other liabilities approximate fair value due to their short-term maturities. Refer to Note 7 regarding the impairment of developed technology and IPR&D and Note 10 regarding fair value measurements and inputs of warrants.

Recent Accounting Pronouncements

New accounting standards adopted by the Company in 2023 are discussed below or in the related notes, where appropriate.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which is intended to provide financial statement users with more useful information about expected credit losses on financial assets held by a reporting entity at each reporting date. In May 2019, the FASB issued ASU No. 2019-05, which amended the new standard by providing targeted transition relief. The new guidance replaces the existing incurred loss impairment methodology with a methodology that requires consideration of a broader range of reasonable and supportable forward-looking information to estimate all expected credit losses. In November 2019, the FASB issued 2019-11, which amended the new standard by providing additional clarification. This guidance is effective for the fiscal years and interim periods within those years beginning after December 15, 2022. This guidance became effective on January 1, 2023 and did not have a material impact to the consolidated financial statements.

New accounting standards not yet adopted are discussed below.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires entities to provide additional information in the rate reconciliation and additional disaggregated disclosures about income taxes paid. This guidance requires public entities to disclose in their rate reconciliation table additional categories of information about federal, state, and foreign income taxes and to provide more details about the reconciling items in some categories if the items meet a quantitative threshold. The guidance is effective for annual periods beginning after December 15, 2024. The Company does not expect the adoption of this guidance to impact its financial statements, but the guidance will impact its income tax disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The amendments require disclosure of significant segment expenses and other segment items and requires entities to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The amendment also requires disclosure of the title and position of the chief operating decision maker ("CODM") and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. This guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application is required, and early adoption is permitted. The Company is currently evaluating the impact the guidance will have on its consolidated financial statements.

(3) Liquidity and Management's Plans

The Company currently does not generate revenue sufficient to offset operating costs and anticipates such shortfalls to continue, primarily due to the introduction of GLP-1 pharmaceuticals, which has taken a significant market share of the medical treatments for obesity. As of December 31, 2023, the Company had net working capital of approximately $6.5 million, primarily due to cash and cash equivalents and restricted cash of $4.6 million. The Company's principal source of liquidity as of December 31, 2023, consisted of approximately $4.5 million of cash and cash equivalents, and $1.7 million of accounts receivable. The Company completed multiple public offerings during 2023, which the Company raised over $17.6 million in cash and cash equivalents after deducting underwriting expenses, commissions and offering expenses. Based on our available cash resources, we may not have sufficient cash on hand to fund our

current operations for more than 12 months from the date of filing the Company's annual report on Form 10-K for the fiscal year ended December 31, 2023. This condition raises substantial doubt about our ability to continue as a going concern.

The Company's anticipated operations include plans to (i) grow sales and operations of the Company with the Lap-Band product line both domestically and internationally as well as to obtain cost savings synergies, (ii) introduce to the market Lap-Band 2.0 FLEX, (iii) continue development of the Diabetes Bloc-Stim Neuromodulation ("DBSN") device, (vi) identifying strategic merger and acquisition alternatives, (v) seek opportunities to find strategic partners to leverage our intellectual property portfolio and custom development services to provide third-party sales and licensing opportunities, and (vi) explore and capitalize on synergistic opportunities to expand our portfolio and offer future minimally invasive treatments and therapies in the obesity continuum of care. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing, and product development activities. If managements' plans don't develop, and the Company doesn't get additional cash raises, at the current burn rate, management expects to run out of cash during the fourth quarter of 2024.

The Company has incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately $635.6 million. The Company also expects to incur a net loss and negative cash flows from operations for 2024.

The Company will be required to raise additional capital, however, there can be no assurance as to whether additional financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, it would have a negative impact on the Company's financial condition and could force the Company to delay, limit, reduce, or terminate product development or future commercialization efforts or grant rights to develop and market product candidates or testing products that the Company would otherwise plan to develop.

Therefore, the plans cannot be deemed probable of being implemented. As a result, the Company's plans do not alleviate substantial doubt about our ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

COVID-19 and Supply Chain Disruptions Risk and Uncertainties

The impact of the COVID-19 outbreak has subsided substantially in the U.S. but continues to result in reduced activity levels outside of the U.S., such as continued restrictions on travel and business operations and advising or requiring individuals to limit or forego their time outside of their homes or places of business.

In response to the global supply chain instability and inflationary cost increases, we continue to take action to minimize, as much as possible, any potential adverse impacts by working closely with our suppliers to closely monitor the availability of raw materials, lead times, and freight carrier availability.

We continuously monitor domestic and global economic conditions, potential outbreaks in viruses that may impact the medical field, and introduction of alternative procedures, pharmaceuticals and weight loss trends that may impact our business. With this information, we develop new models and approaches to achieve the best outcomes.

(4) Supplemental Balance Sheet Information

Inventory

	December 31, 2023	December 31, 2022
Raw materials	$1,020	$ 832
Sub-assemblies	1,379	864
Finished goods	1,342	1,915
Total inventory	$3,741	$3,611

Prepaid expenses and other current assets:

	December 31, 2023	December 31, 2022
Prepaid insurance	$110	$ 78
Patents	13	—
Prepaid advertising and marketing	41	3
Taxes	47	—
Other current assets	126	84
Total prepaid expenses and other current assets	$337	$165

Accrued and other liabilities:

	December 31, 2023	December 31, 2022
Payroll and benefits	$ 701	$1,829
Accrued legal settlements	200	1,775
Customer deposits	639	510
Taxes	61	119
Accrued professional	155	316
Other liabilities	58	491
Total accrued and other liabilities	$1,814	$5,040

(5) Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2023	2022
Machinery and equipment	$ 61	$ 582
Furniture and equipment	5	27
Computer hardware and software	78	136
Tooling and molds	6	199
Leasehold improvements	—	19
Construction in progress	—	66
	150	1,029
Less accumulated depreciation and amortization	(90)	(331)
Property and equipment, net	$ 60	$ 698

Depreciation expense for the years ended December 31, 2023 and 2022, was approximately $121 thousand and $330 thousand, respectively.

During the year ended December 31, 2023 the Company determined the carrying value of the property plant and equipment had been impaired due to the current financial condition of the Company and recognized a non-cash impairment charge of $0.5 million. The fair value was determined by estimating the amount the Company could receive if they were to sell the assets.

(6) Intangible Assets

During the year ended December 31, 2023 the Company determined the carrying value of the developed technology and trademarks/tradenames had been impaired due to the financial condition of the Company and recognized a non-cash impairment charge of $0.2 million, which fully impaired the intangible assets.

The consolidated intangible assets at December 31, 2022 consist of the following:

	December 31, 2022			
	Weighted Average Useful Life (years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Finite-lived intangible assets:				
Developed technology	10.0	$5,989	$(5,805)	$184
Trademarks/Tradenames	10.0	462	(386)	76
Total		$6,451	$(6,191)	$260

The gross amount and accumulated impairment loss of indefinite-lived intangible assets are as follows (in thousands):

	December 31,	
	2023	2022
Indefinite-lived intangible assets		
Gross amount	$ —	$ 20,721
Accumulated impairment loss	—	(20,721)
Total Indefinite-lived intangible assets	$ —	$ —

Amortization expense for the years ended December 31, 2023 and 2022, was approximately $33 thousand and $1.8 million, respectively.

The Company had impaired all of its remaining intangible assets during 2023, therefore there is no future projection of amortization expense at December 31, 2023.

(7) Impairment of Intangible Assets and Goodwill

During the year ended December 31, 2023, the Company determined a triggering event occurred due to the decline in the Company's market capitalization, and as such, the Company performed an impairment analysis of the long-lived assets. It was determined that the carrying value of the developed technology and trademarks/tradenames had been fully impaired and recognized a non-cash impairment charge of $0.2 million on the consolidated statement of operations for the year ended December 31, 2023 and a consolidated balance sheet value as of December 31, 2023, of zero.

As of December 31, 2022, the Company determined a triggering event occurred due to the decline in the Company's market capitalization, and as such, the Company performed an impairment analysis of the long-lived assets. It was determined the developed technology related to the Obalon Balloon was fully impaired, as the Company has not been able to start up production or find a partner to manufacture the Obalon Balloon system. Based on this the Company has no current projections for revenues related to the

Obalon Balloon and has fully impaired the asset of approximately $2.4 million. Additionally, due to the continuance of COVID-19, the Company has revised the near-term projected revenues related to the Lap-Band asset group and has recognized an impairment charge to both the developed technology and tradenames of approximately $8.4 million and $0.5 million, respectively. The fair value of the Lap-Band developed technology was estimated using an income approach using Level 3 assumptions which included discounting projected future net cash flows to their present value, with a discount rate of 17.9%.

The Company also determined a triggering event occurred, as the Company elected to stop the clinical trials for the ReShape Vest and was closing out the previous trial that occurred, as significant additional clinical work and cost would be required to achieve regulatory approval. Additionally, the Company currently does not plan to pursue the development of the ReShape Vest. As such, the Company determined the carrying value of the IPR&D asset and related trademarks were impaired and recognized non-cash impairment charge of approximately $6.9 million and $0.5 million, respectively, on the consolidated balance sheet as of December 31, 2022, which reduced the value of these assets to zero.

(8) Leases

The Company had a noncancelable operating lease for office and warehouse space in San Clemente, which expired June 30, 2023. The Company also had an operating lease and warehouse space in Carlsbad, California, which expired June 30, 2022. On March 13, 2023, the Company entered into a lease for approximately 5,038 square feet of office and warehouse space at 18 Technology Drive, Suite 110, Irvine, California 92618 and relocated our principal executive offices from our former San Clemente, California location to the Irvine, California location. The Irvine, California lease has a term of 36 months commencing on May 1, 2023.

The Company does not have any short-term leases or financing lease arrangements and the effects of any lease modifications have not been material. Lease and non-lease components are accounted for separately.

The Company determines the lease term as the noncancelable period of the lease, and may include options to extend or terminated the lease when reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the balance sheet. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments. Right-of-use assets also include any lease payments made at or before lease commencement and any initial direct costs incurred, and exclude any lease incentives received.

Operating lease costs for the years ended December 31, 2023 and 2022, were $0.3 million and $0.7 million, respectively. Variable lease costs were not material.

Supplemental information related to operating leases is as follows:

Balance Sheet information	December 31, 2023	December 31, 2022
Operating lease ROU assets	$250	$171
Operating lease liabilities, current portion	$111	$171
Operating lease liabilities, long-term portion	151	—
Total operating lease liabilities	$262	$171

Cash flow information for the twelve months ended December 31,	2023	2022
Cash paid for amounts included in the measurement of operating leases liabilities	$228	$560

Maturities of operating lease liabilities at December 31, 2023 were as follows:

2024	111
2025	115
2026	59
Total lease payments	285
Less: imputed interest	23
Total lease liabilities	$262
Weighted-average remaining lease term at end of period (in years)	2.4
Weighted-average discount rate at end of period	6.9%

(9) Equity

The Company may issue preferred stock, common stock, or both, in connection with underwritten public offerings, registered direct offerings, private placements or business acquisitions. Such issuances of equity typically include the issuance or sale of warrants to purchase common stock. Certain issuances of convertible preferred stock and warrants may contain anti-dilutive features apart from customary adjustments for splits and reverse splits of common stock (collectively, "down round features"). When a series of convertible preferred stock contains this non-standard down round feature, the Company is required to adjust the conversion price in the event of future stock sales at a lower unit price. When warrants issued in connection with an equity transaction contain, or are amended to contain, this non-standard down round feature, the Company is required to adjust the exercise price upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price and evaluate and account for the value attributable to the reduced warrant exercise price. In the event down round adjustments are triggered, the values attributable to the adjustment to the convertible preferred stock conversion price and warrant exercise price are recorded as an increase to additional paid-in capital and increase to accumulated deficit.

All series of the Company's convertible preferred stock are classified in stockholders' equity, including those with the down round feature, when applicable to the equity transaction.

Warrants to purchase common stock are classified in stockholders' equity, including those issued with the down round feature, as they are both indexed to the Company's own stock and meet the scope exception in ASC 815 "Derivatives and Hedging."

The Company had the following equity transactions during the years ended December 31, 2023 and 2022:

November 2023 Exercise of Warrants for Common Stock

On November 21, 2023, the Company entered into a warrant exercise agreement with an existing accredited investor to exercise certain outstanding warrants to purchase up to an aggregate of 92,802 shares of the Company's common stock (the "Existing Warrants"). In consideration for the immediate exercise of the Existing Warrants for cash, the exercising holders received new unregistered warrants to purchase up to an aggregate of 185,604 shares (equal to 200% of the shares of common stock issued in connection with the Exercise) of the Company's common stock (the "New Warrants") in a private placement. In connection with the Exercise, the Company also agreed to reduce the exercise price of the Existing Warrants from $14.52 to $13.34 and to reduce the exercise price of the remaining unexercised warrants from either $19.14 or $14.52 to $13.34 per share, which is equal to the most recent closing price of the Company's common stock on The Nasdaq Capital Market prior to the execution of the warrant exercise agreement.

The New Warrants will become exercisable six months after issuance at an exercise price of $13.34 per share and have a term of exercise equal to five and one-half years. The Existing Warrants and the New Warrants each include a beneficial ownership limitation that prevents the investor from owning more than 9.99%, with respect to the Existing Warrants, and 4.99%, with respect to the New Warrants, of the Company's outstanding common stock at any time.

The gross proceeds to the Company from the Exercise was approximately $1.2 million, prior to deducting warrant inducement agent fees and estimated offering expenses. The Company intends to use the remainder of the net proceeds for commercial growth, working capital and general corporate purposes.

Maxim Group LLC ("Maxim") acted as the exclusive warrant inducement agent and financial advisor to the Company for the Exercise. The Company agreed to pay Maxim an aggregate cash fee equal to 6.5% of the gross proceeds received by the Company from the Exercise.

October 2023 Securities Offering

On October 3, 2023, the Company completed a Securities Purchase Agreement with certain investors pursuant to which the Company agreed to issue and sell to the investors (i) 30,518 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), (ii) warrants to purchase up to 235,345 shares of Common Stock at an initial exercise price of $19.14 per share (the "Common Warrants") and (iii) pre-funded warrants to purchase 126,380 shares of Common Stock at an exercise price of $0.001 per share. The securities were sold as part of units at a price of $19.14 per unit or, with respect to the units including pre-funded warrants, $19.08 per unit. In connection with the offering, the Company also agreed that certain existing warrants to purchase up to an aggregate of 16,644 shares of Common Stock at an exercise price of $178.06 per share and warrants to purchase up to an aggregate of 6,595 shares of Common Stock at an exercise price of $464.00 per share that were previously issued to one of the investors, were amended effective upon the closing of the Offering so that the amended warrants have an exercise price of $19.14 per share. The net proceeds from the offering were approximately $2.8 million, after deducting the placement agent fees and before deducting offering expenses.

April 2023 Securities Offering

On April 20, 2023, the Company entered into a Securities Purchase Agreement with a certain institutional investor, pursuant to which the Company agreed to issue and sell to the Investor in a registered direct offering (i) 5,025 shares of the Company's common stock, par value $0.001 per share, and (ii) pre-funded warrants to purchase an aggregate of 8,782 shares of Common Stock. Each share of common stock was sold at a price of $178.06 per share and each Pre-funded Warrant was sold at an offering price of $178.00 per share underlying such Pre-funded Warrants, for aggregate gross proceeds of approximately $2.5 million before deducting the placement agent's fees and the offering expenses. The Company has been using the net proceeds of this offering to continue implementation of its growth strategies, for working capital and general corporate purposes. In addition, under the Purchase Agreement, the Company also agreed to issue and sell to the Investor in a concurrent private placement warrants to purchase an aggregate of 13,806 shares of common stock.

In connection with the Offering, the Company also agreed that certain existing warrants to purchase up to an aggregate of 2,839 shares of Common Stock that were issued to the Investor, at an exercise price of $870.00 per share, were amended effective upon the closing of the Offering so that the amended warrants have an exercise price of $178.06. The Company's exclusive placement agent in connection with the Offering, Maxim Group LLC, received a cash fee equal to 7.0% of the gross proceeds received by the Company from the sale of the securities in Offering, as well as reimbursement for certain expenses, and warrants to purchase up to 691 shares of Common Stock, which is equal to 5.0% of the aggregate amount of shares of Common Stock issued in the Offering, at an exercise price of $196.04 per share.

February Public Offering of Common Stock and Warrants

On February 8, 2023, the Company closed a public offering of 21,983 units, with each consisting of one share of its common stock, or one pre-funded warrant to purchase one share of its common stock, and one warrant to purchase one and one-half shares of its common stock. Each unit was sold at public offering price of $464.00. The warrants in the units are immediately exercisable at a price of $464.00 per share and expire five years from the date of issuance. Alternatively, each warrant can be exercised pursuant to the "alternative cashless exercise" provision, to which the holders would receive an aggregate number of shares of common stock equal the product of (x) the aggregate number of shares of common stock that would be issuable upon a cash exercise and (y) 0.50. For purposes of clarity, one common warrant to purchase one and one-half shares would be exercisable for 0.75 shares under this alternative cashless exercise

provision. The shares of common stock (or pre-funded warrants in lieu thereof) and accompanying warrants were only purchasable together in this offering but were issued separately and immediately separable upon issuance. As of December 31, 2023, warrants to purchase 28,869 shares of common stock have been exercised under the alternative cashless exercise for a total of 14,402 shares of common stock.

Gross proceeds, before deducting underwriting discounts and commissions and estimated offering expenses, are approximately $10.2 million. The Company has been using the net proceeds of this offering to continue implementation of its growth strategies, for working capital and general corporate purposes.

The Company also granted the underwriters an option to purchase an additional 3,298 shares of common stock and/or additional warrants to purchase up to 4,947 shares of common stock, to cover over-allotments, of which Maxim Group LLC exercised its option to purchase additional warrants to purchase 4,947 shares of common stock.

November 2022 Sale of Common Stock

On November 8, 2022, the Company entered into a securities purchase agreement with an existing accredited investor, to issue and sell 826 shares of common stock, 2,500 shares of Series D Mirroring Preferred stock for $0.001 per share, which automatically terminated subsequent to the shareholder meeting on December 14, 2022, and prefunded warrants to purchase an aggregate of 170 shares of common stock. Each share of common stock was sold at a price of $754.00 per share, and each pre-funded warrant was sold at an offering price of $751.00 per share underlying such pre-funded warrants, for aggregate gross proceeds of $750,000 before deducting the placement agent's fees and offering expenses. Under the purchase agreement, the Company also agreed to issue and sell to the investor in a concurrent private placement warrants to purchase an aggregate of 995 shares of common stock. The Company intends to use the remainder of the net proceeds for commercial growth, working capital and general corporate purposes.

In connection with the offering, the Company also entered into a warrant amendment agreement with the investor. Under the warrant amendment agreement, the Company agreed to amend certain existing warrants to purchase up to 1,845 shares of common stock that were previously issued to the investor, with an exercise price of $1,933.14 per share and expiration dates of June 2026 and December 2029, in consideration of their purchase of securities in the offering as follows: (i) lower the exercise price of the existing warrants to $870 per share, (ii) provide the existing warrants as amended, will not be exercisable until six months following the closing date of the offering, and (iii) extend the expiration date of the existing warrants with an expiration date of June 2026 by five and one-half years following the close of the offering.

June 2022 Exercises of Warrants for Common Stock

On June 16, 2022, the Company entered into a warrant exercise agreement with an existing accredited investor to exercise certain outstanding warrants to purchase up to an aggregate of 1,290 shares of common stock. In consideration for the immediate exercise of the existing warrants for cash, the exercising holders received new unregistered warrants to purchase up to an aggregate of 1,290 shares (equal to 100% of the shares of common shares exercised) of the Company's common stock (the "New Warrants") in a private placement pursuant to Section (4)(2) of the Securities Act. In connection with the exercise, the Company also agreed to reduce the exercise price of the existing warrants and 555 remaining unexercised warrants from $17,400.00 to $1,933.14 per share, which is equal to the most recent closing price of the Company's common stock on the Nasdaq prior to the execution of the warrant exercise agreement. For further details see Note 10 below.

The gross proceeds to the Company from the exercise was approximately $2.5 million, prior to deducting warrant inducement agent fees and estimated offering expenses. The Company intends to use the remainder of the net proceeds for commercial growth, working capital and general corporate purposes.

Common Stock Issued Related to Stock Awards and Options

Restricted Stock Units

The Company issued restricted stock units ("RSUs") to certain members of the management and Board of Directors. During the year ended December 31, 2023, the Company issued 44 shares of common stock subject to the vesting of the awards.

During the year ended December 31, 2022, the Company issued 866 shares of common stock subject to the vesting of the awards, of which 496 shares of common stock were related to bonus in-leu of cash. For further details see Note 12.

Exercise of Stock Options

There were no exercises of stock options during the years ended December 31, 2023 and 2022.

Series C Convertible Preferred Stock

The Series C convertible stock has a liquidation preference of $274.88 per share. Holders of the Series C convertible preferred stock have the right to convert their shares into shares of common stock instead of receiving the liquidation preference. The Series C convertible preferred stock is entitled to dividends on an as-if-converted-to-common stock basis if such dividends are paid on shares of common stock. In general, the holders of the Series C convertible preferred stock do not have voting rights, except in connection with director elections.

(10) Warrants

The Company's grants of warrants to purchase common stock are primarily in connection with equity and debt financings. See Note 9 for additional information about equity financings and the related issuance of warrants. Warrant activity was as follows:

	Shares
Balance December 31, 2021	2,398
Issued	2,504[(1)]
Exercised	(1,459)[(2)]
Cancelled	(107)
Balance December 31, 2022	3,336
Issued	619,185[(3)]
Exercised	(353,581)[(4)]
Cancelled	(3)
Balance December 31, 2023	268,937

(1) Warrants issued in 2022 includes: 1,289 reload warrants, 995 common stock purchase warrants, 50 representative's warrants, and 170 pre-funded warrants.

(2) Warrants exercised in 2022 includes: 1,289 reload warrants at an exercise price of $1,933.14 per share, and 170 pre-funded warrants at an exercise price of $2.90 per share.

(3) Warrants issued in 2023 includes: 472,672 common stock purchase warrants, of which 37,921 are classifies as liability warrants, 136,713 pre-funded warrants, and 9,800 representative's warrants.

(4) Warrants exercised in 2023 includes: 188,000 common stock purchase warrants at an exercise price range of $19.14 per share and $13.34 per share, 28,869 common stock purchase warrants (liability warrants) exercised with the alternative cash less option, 136,712 pre-funded warrants at an exercise price range of $0.06 and $0.01 per share.

Warrant Assumptions — 2023 Warrants Issued

The following table provides the assumptions used to calculate the fair value of the new warrants issued during 2023, using a Black-Scholes model:

	Warrants	Strike Price	Volatility	Expected Term	Risk Free Rate
Pre-funded warrants – February 2023	1,552	$ 0.01	96.5%	5.0	3.78%
Representative's warrants – February 2023	1,265	$510.40	96.5%	5.0	3.79%
Common stock warrants – April 2023	13,806	$178.06	88.4%	5.5	3.56%
Pre-funded warrants – April 2023	8,782	$ 0.01	88.4%	5.5	3.56%
Representative's warrants – April 2023	691	$196.04	96.3%	5.0	3.57%
Common stock warrants – October 2023	235,345	$ 19.14	89.1%	5.0	4.74%
Pre-funded warrants – October 2023	126,380	$ 0.06	89.1%	5.0	4.74%
Representative's warrants – October 2023	7,845	$ 21.05	89.2%	5.0	4.74%

The following table provides the assumptions used to calculate the fair value of the new warrants issued during 2023, using a Monte Carlo model:

	Warrants	Strike Price	Volatility	Expected Term	Risk Free Rate
Common stock warrants – November 2023	185,604	$13.34	86.9%	5.5	4.40%

The following table provides the assumptions used in the bifurcated Black-Scholes option pricing model for the common stock purchase warrants classified as a liability:

	Cash Exercise	Cashless Exercise
Stock Price	$342.49	$342.49
Exercise Price	$928.00	$ 0.00
Term (years)	5.00	5.00
Volatility	96.50%	96.50%
Risk Free Rate	3.784%	3.784%
Dividend Yield	0%	0%

The following table presents the changes in the fair value of the liability warrants:

	Common Stock Purchase Warrants
Fair value as of February 8, 2023 (issuance date)	$10,363
Fair value of liability warrants in excess of proceeds, at issuance	(164)
Exercises of liability warrants	(6,249)
Gain on changes in fair value of liability warrants	(3,878)
Fair value as of December 31, 2023	$ 72

Warrant Assumptions — 2022 Warrants Issued

The following table provides the assumptions used to calculate the fair value of the Series G warrants issued during 2022, using a Black-Scholes model:

	Warrants	Strike Price	Volatility	Expected Term	Risk Free Rate
Reload warrants – June 2022	1,290	$1,933.14	64.8%	7.5	3.32%
Reload warrants – November 2022	995	$ 870.00	84.3%	5.5	4.21%
Representative's warrants	50	$ 870.00	84.3%	5.0	4.23%
Pre-funded warrants	170	$ 2.90	84.3%	5.5	4.21%

(11) Revenue Disaggregation and Operating Segments

The following table presents the Company's revenue disaggregated by geography:

	Year Ended December 31,	
	2023	2022
United States	$7,134	$ 9,230
Australia	526	688
Europe	956	1,252
Rest of world	62	70
Total revenue	$8,678	$11,240

Operating Segments

The Company conducts operations worldwide and is managed in the following geographical regions: United States, Australia, Europe and Rest of World (primarily in the Middle East). All regions sell the Lap-Band product line, which consisted of nearly all our revenue and gross profit for the years ended December 31, 2023 and 2022. During the second half of 2020 the Company launched ReShapeCare, which had minimal revenue for the years ended December 31, 2023 and 2022. During the fourth quarter of 2023, the Company placed the continued development of ReShapeCare on hold indefinitely. There was no revenue or gross profit recorded for the DBSN device in 2023 or 2022 because this product is still in the development stage. During June 2021, the Company merged with Obalon, which had no revenues for the years ended December 31, 2023 and 2022.

The Company has one operating segment based on the financial information provided to the Chief Operating Decision Maker (the Chief Executive Officer, or "CODM"). The Company's CODM evaluates segment performance based on revenue and gross profit at the consolidated level. The CODM does review revenue based on domestic and international. As such, the Company believes reporting revenue based on territory is useful to the user of the financial statements.

(12) Stock-based Compensation

The ReShape Lifesciences Inc. 2022 Equity Incentive Plan (the "Plan") became effective December 14, 2022, and provides for the grant of stock options or other stock-based awards to employees, officers, non-employee directors and outside consultants of the Company. The maximum number of shares of common stock that will be available for issuance under this Plan was originally 105,000 shares; provided however, that the aggregate number of shares that may be issued under all awards under the Plan will automatically increase on an annual basis on the first day of each year beginning in 2024 such that the aggregate number of shares that may be issued under all awards under this Plan equals 15% of the total number of shares of Common Stock, on a converted basis, on the last day of the immediately preceding fiscal year. Under the 2003 Stock Incentive Plan, as amended in 2018 (the "Prior Plan"), as of January 1, 2023, there were 110,798 shares available.

The Plan is administered by the committee, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. Options granted under the Plan expire no later than ten years from the date of grant. The exercise price of each option may not be less than 100% of the fair market value of the common stock at the date of grant, except if an

incentive stock option is granted to a Plan participant possessing more than 10% of the Company's common stock, as defined by the Plan, the exercise price may not be less than 110% of the fair value of the common stock at the date of grant. Employee stock options generally vest over four years.

Stock Options

A summary of the status of the Company's stock options are as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	306	$23,117.06		$ —
Options granted	194	3,422.00		
Options exercised	—	—		
Options cancelled	(130)	8,071.28		
Outstanding at December 31, 2022	370	18,075.70		$ —
Options granted	—	—		
Options exercised	—	—		
Options cancelled	(107)	8,661.72		
Outstanding at December 31, 2023	263	21,909.50	6.4	$ —
Exercisable at December 31, 2023	213	25,839.58	6.0	—
Vested and expected to vest at December 31, 2023	274	21,909.50	6.4	—

As of December 31, 2023, stock options under the Plan that were outstanding, exercisable and vested, and expected to vest, had no intrinsic value. The unrecognized share-based expense at December 31, 2023 was $0.1 million and will be recognized over a weighted average period of 1.8 years.

Stock option awards outstanding under the Company's incentive plans have been granted at exercise prices that are equal to the market value of its common stock on the date of grant. Such options generally vest over a period of four years and expire at ten years after the grant date. The Company recognizes compensation expense ratably over the vesting period. The Company uses a Black-Scholes option-pricing model to estimate the fair value of stock options granted, which requires the input of both subjective and objective assumptions as follows:

Expected Term — The estimate of expected term is based on the historical exercise behavior of grantees, as well as the contractual life of the options granted.

Expected Volatility — The expected volatility factor is based on the volatility of the Company's common stock.

Risk-free Interest Rate — The risk-free interest rate is determined using the implied yield for a traded zero-coupon U.S. Treasury bond with a term equal to the expected term of the stock options.

Expected Dividend Yield — The expected dividend yield is based on the Company's historical practice of paying dividends on its common stock.

The Company did not issue any stock options during the year ended December 31, 2023. The Company's weighted average assumptions used to estimate fair value of stock options granted during the year ended December 31, 2022 were as follows:

Risk-free interest rate	2.67%
Expected term (in years)	6.25
Expected dividend yield	0%
Expected volatility	80.40%

Restricted Stock Units

A summary of the status of the Company's unvested RSUs are as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested RSUs at December 31, 2021	591	$ 12,644.00
Granted	566	981.36
Vested[(1)]	(865)	(5,651.52)
Cancelled/Forfeited	(213)	(11,013.04)
Unvested RSUs at December 31, 2022	79	10,100.70
Granted	—	—
Vested[(1)]	(54)	(11,298.98)
Cancelled/Forfeited	—	—
Non-vested RSUs at December 31, 2023	25	$ 7,505.04

(1) At December 31, 2023 and 2022, there were 2 and 5 shares of common stock, respectively, related to RSU awards that have vested and the shares were not released to the participants subsequently. Additionally, during the year ended December 31, 2023 due to a decline in our stock price 8 shares of common stock were not issued in order to cover employee taxes.

The fair value of each RSU is the closing price on the Nasdaq of the Company's common stock on the date of grant. Upon vesting, a portion of the RSU award may be withheld to satisfy the statutory income tax withholding obligation. The remaining RSUs will be settled in shares of the Company's common stock after the vesting period. The unrecognized compensation cost related to RSUs at December 31, 2023 was $0.6 million and is expected to be recognized over a period of 1.2 years.

Compensation expense related to stock options was recognized as follows:

	Year Ended December 31,	
	2023	2022
Sales and marketing	$107	$ 280
General and administrative	451	1,494
Research and development	209	313
Total stock-based compensation expense	$767	$2,087

(13) Income Taxes

Income tax expense (benefit) consists of the following:

	Year ended December 31,	
	2023	2022
Deferred:		
Federal	$—	$(293)
State	—	(76)
Foreign	28	(54)
Deferred income tax benefit	28	(423)

	Year ended December 31,	
	2023	2022
Current:		
Federal	—	30
State	7	9
Foreign	17	4
Total income tax expense (benefit), net	$52	$(380)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended December 31,	
	2023	2022
Income tax benefit at U.S. federal statutory rate	21.0%	21.0%
State income tax benefit, net of federal benefit	5.9%	3.8%
Stock warrant valuation	9.7%	—%
Other permanent differences	(2.2)%	(1.9)%
Change in state tax rate	4.3%	0.3%
Foreign rate differential	2.7%	(0.2)%
Net operating loss true up	(6.3)%	—%
Other adjustments	(0.8)%	2.8%
Change in valuation allowance	(34.8)%	(25.0)%
Effective income tax rate	(0.5)%	0.8%

A reconciliation of the beginning and ending amount of uncertain tax positions are as follows:

	2023	2022
Uncertain gross tax positions, January 1	$1,052	$1,052
Current year tax positions	—	—
Increase in prior year tax positions	—	—
Settlements	—	—
Lapse of statute of limitations	—	—
Uncertain gross tax positions, December 31	$1,052	$1,052

The components of deferred tax assets and liabilities are as follows:

	December 31,	
	2023	2022
Deferred tax assets:		
Start-up costs	$ 1,096	$ 1,137
Capitalized research and development costs	170	272
Reserves and accruals	751	1,157
Property and equipment	56	—
Intangible assets	4,420	4,597
Research and development credit	2,492	2,492
Lease liability	70	43
Net operating loss carryforwards	67,930	63,424
State and local taxes	2	2
Total gross deferred tax assets	76,987	73,124

	December 31,	
	2023	2022
Valuation allowance	(76,895)	(72,945)
Deferred tax assets, net of valuation allowance	92	179
Property and equipment	—	(80)
Intangible assets	—	—
Operating lease right-of-use assets	(64)	(43)
Total gross deferred tax liabilities	(64)	(123)
Deferred income taxes, net	$ 28	$ 56

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Based on the level of historical losses and projections of losses in future periods, the Company provided a valuation allowance at both December 31, 2023 and 2022. The remaining net deferred tax asset at December 31, 2023 is the remaining balance of the Netherlands net operating loss. A valuation allowance is not applicable to this entity, as they historically produce income and utilize their net operating loss carryforward. In 2022, the indefinite-lived intangible asset became fully impaired. The Company has a policy that NOL's are shown gross with valuation allowances with respect to IRC 382 limitations.

As of December 31, 2023 and 2022, the Company had U.S. federal net operating loss carryforwards of $218.9 million and $207.9 million, respectively. Of the total U.S. federal net operating loss carryforwards at December 31, 2023. Losses generated beginning in 2018 will carryover indefinitely. The Company had state net operating loss carryforwards of $348.7 million and $329.1 million at December 31, 2023 and 2022, respectively and had foreign net operating loss carryforwards of $0.2 million at both December 31, 2023 and 2022. Net operating loss carryforwards of the Company are subject to review and possible adjustment by the taxing authorities. With certain exceptions (e.g. the net operating loss carryforwards), the Company is no longer subject to U.S. federal, state or local examinations by tax authorities for years prior to 2016. There are no tax examinations currently in progress.

The Company's ability to utilize its net operating loss carryforwards, tax credits, and built-in items of deduction, including capitalized start-up costs and research and development costs, has been, and may continue to be substantially limited due to ownership changes. These ownership changes limit the amount of net operating loss carryforwards, credits and built-in items of deduction that can be utilized annually to offset future taxable income. In general, an ownership change, as defined in IRC Section 382, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups. Due to the valuation allowance against deferred tax assets at December 31, 2023, the net effect of any further limitation will have no impact on results of operations.

The Company is in the process of completing an IRC Section 382 analysis for the year ended December 31, 2023. The Company believes it experienced an ownership change during 2023 that will result in further limitations on the utilization of its net operating losses. The 2023 ownership change is expected to result in further net operating losses to expire unused. The Company reflected the estimated impact of the 2023 ownership change in the deferred tax table and gross net operating loss carryforwards within this footnote.

The Company has adopted accounting standards which prescribe a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company had no amounts of unrecognized tax benefits that, if recognized, would affect its effective income tax rate for the years ended December 31, 2023 and 2022. The Company's policy is to classify interest and penalties related to income tax expense as tax expense. As of December 31, 2023, the Company had no amount accrued for the payment of interest and penalties related to unrecognized tax benefits.

The Inflation Reduction Act (IRA) was enacted on August 16, 2022 and includes a new corporate alternative minimum tax based on book income, an excise tax on stock buybacks, and other items such as tax incentives for energy and climate initiatives. There is no impact to the Company at this time, however this may change depending on each year's differing facts and activities. The Company will continue to monitor this over time.

(14) Commitments and Contingencies

Employee Arrangements and Other Compensation

Certain members of management are entitled to severance benefits payable upon termination following a change in control, which would approximate $0.8 million at December 31, 2023. The Company also has agreements with certain employees to pay bonuses based on targeted performance criteria. As of December 31, 2023 and 2022, approximately $15 thousand and $0.3 million, respectively, was accrued for performance bonuses, which is included in accrued liabilities in the consolidated balance sheets.

Purchase Commitments

The Company generally purchases its products and accessories from a limited group of third-party suppliers through purchase orders. The Company had $0.9 million of inventory open purchase orders as of December 31, 2023, for orders being issued to supplies for which the Company has not received the goods or services and which are expected to be fulfilled within one year. These purchase commitments were made to secure better pricing and to ensure the Company will have the necessary inventory to meet anticipated near term demand. Although open purchase orders are considered enforceable and legally binding, the Company may be able to cancel, reschedule, or adjust requirements prior to supplier fulfillment.

Litigation

On August 6, 2021, Cowen and Company, LLC filed a complaint against ReShape, as successor in interest to Obalon Therapeutics, in the Supreme Court of the State of New York based on an alleged breach of contract arising out of Cowen's prior engagement as Obalon's financial advisor. The complaint alleges that Cowen is entitled to be paid a $1.35 million fee in connection with ReShape's merger with Obalon under the terms of Cowen's engagement agreement with Obalon. The complaint also sought reimbursement of Cowen's attorneys' fees and interest in connection with its claim. On May 11, 2023, the Supreme Court of the State of New York issued the final judgement in favor of Cowen & Company in the amount of $1.35 million, plus interest at the statutory rate of 9% per annum from June 16, 2021 until judgement is paid in full, and reimbursement of $675,000 of Cowen's attorneys' fees, with $275,000 to be paid upfront, $200,000 paid after six months and $200,000 paid after 12 months. As of December 31, 2023, the Company has paid the $1.35 million judgement, including related interest, and first $275,000 installment of Cowen's attorneys' fees. At December 31, 2023, $200 thousand of attorneys' fees were included as accrued expenses.

The Company is not aware of any pending or threatened litigation against it that could have a material adverse effect on the Company's business, operating results or financial condition, other than what was disclosed above. The medical device industry in which the Company operates is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result the Company may be involved in various legal proceedings from time to time.

Product Liability Claims

The Company is exposed to product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Management believes any losses that may occur from these matters are adequately covered by insurance, and the ultimate outcome of these matters will not have a material effect on the Company's financial position or results of operations. The Company is not currently a party to any product liability litigation and is not aware of any pending or threatened product liability litigation that could have a material adverse effect on the Company's business, operating results or financial condition.

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RESHAPE LIFESCIENCES INC.

Condensed Consolidated Balance Sheets
(unaudited)
(dollars in thousands, except per share amounts)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 743	$ 4,459
Restricted cash	100	100
Accounts and other receivables (net of allowance for doubtful accounts of $866 and $804, respectively)	1,344	1,659
Inventory	2,934	3,741
Prepaid expenses and other current assets	217	337
Total current assets	5,338	10,296
Property and equipment, net	43	60
Operating lease right-of-use assets	177	250
Deferred tax asset, net	28	28
Other assets	29	29
Total assets	$ 5,615	$ 10,663
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,105	$ 1,689
Accrued and other liabilities	1,643	1,814
Warranty liability, current	163	163
Operating lease liabilities, current	114	111
Total current liabilities	4,025	3,777
Operating lease liabilities, noncurrent	77	151
Common stock warrant liabilities	26	72
Total liabilities	4,128	4,000
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, 10,000,000 shares authorized:		
Series C convertible preferred stock, $0.001 par value; 95,388 shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized at September 30, 2024 and December 31, 2023; 704,697 and 404,437 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	642,518	642,325
Accumulated deficit	(640,943)	(635,574)
Accumulated other comprehensive loss	(88)	(88)
Total stockholders' equity	1,487	6,663
Total liabilities and stockholders' equity	$ 5,615	$ 10,663

See accompanying notes to Condensed Consolidated Financial Statements.

RESHAPE LIFESCIENCES INC.

Condensed Consolidated Statements of Operations
(unaudited)
(dollars in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	$ 2,292	$ 2,155	$ 6,201	$ 6,696
Cost of revenue	853	867	2,463	2,990
Gross profit	1,439	1,288	3,738	3,706
Operating expenses:				
Sales and marketing	719	1,791	2,408	6,150
General and administrative	2,082	2,058	6,074	8,724
Research and development	399	542	1,282	1,576
Impairment of long-lived assets	—	777	—	777
Gain on disposal of assets, net	—	—	—	(33)
Total operating expenses	3,200	5,168	9,764	17,194
Operating loss	(1,761)	(3,880)	(6,026)	(13,488)
Other expense (income), net:				
Interest income, net	—	(5)	(13)	(9)
Gain on changes in fair value of liability warrants	(27)	(412)	(46)	(3,850)
Gain on extinguishment of debt	—	—	(429)	—
Loss (gain) on foreign currency exchange, net	(50)	68	(10)	47
Other	(109)	—	(193)	(8)
Loss before income tax provision	(1,575)	(3,531)	(5,335)	(9,668)
Income tax expense	6	3	34	21
Net loss	$ (1,581)	$ (3,534)	$ (5,369)	$ (9,689)
Net loss per share – basic and diluted:				
Net loss per share – basic and diluted	$ (3.11)	$ (59.36)	$ (11.94)	$(199.98)
Shares used to compute basic and diluted net loss per share	508,851	59,538	449,614	48,451

See accompanying notes to Condensed Consolidated Financial Statements.

RESHAPE LIFESCIENCES INC.

Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(dollars in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$(1,581)	$(3,534)	$(5,369)	$(9,689)
Foreign currency translation adjustments	1	1	—	(6)
Other comprehensive income (loss), net of tax	1	1	—	(6)
Comprehensive loss	$(1,580)	$(3,533)	$(5,369)	$(9,695)

See accompanying notes to Condensed Consolidated Financial Statements.

RESHAPE LIFESCIENCES INC.

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(dollars in thousands)

	Three Months Ended September 30, 2024							
	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance June 30, 2024	95,388	$ —	506,680	$ —	$642,486	$(639,362)	$(89)	$ 3,035
Net loss	—	—	—	—	—	(1,581)	—	(1,581)
Other comprehensive income, net of tax	—	—	—	—	—	—	1	1
Issuance of common stock pursuant to reverse stock split	—	—	198,014	—	—	—	—	—
Stock compensation	—	—	—	—	32	—	—	32
Issuance of stock from RSUs	—	—	3	—	—	—	—	—
Balance September 30, 2024	95,388	$ —	704,697	$ —	$642,518	$(640,943)	$(88)	$ 1,487

	Nine Months Ended September 30, 2024							
	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance December 31, 2023	95,388	$ —	404,437	$ —	$642,325	$(635,574)	$(88)	$ 6,663
Net loss	—	—	—	—	—	(5,369)	—	(5,369)
Issuance of common stock pursuant to reverse stock split	—	—	198,014	—	—	—	—	—
Stock compensation	—	—	—	—	169	—	—	169
Issuance of stock from RSUs	—	—	5	—	—	—	—	—
Exercise of warrants	—	—	102,241	—	24	—	—	24
Balance September 30, 2024	95,388	$ —	704,697	$ —	$642,518	$(640,943)	$(88)	$ 1,487

See accompanying Notes to Condensed Consolidated Financial Statements.

RESHAPE LIFESCIENCES INC.

Condensed Consolidated Statements of Stockholders' Equity (Continued)
(unaudited)
(dollars in thousands)

	Three Months Ended September 30, 2023							
	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance June 30, 2023	95,388	$ —	59,526	$ —	$637,175	$(630,342)	$(95)	$ 6,738
Net loss	—	—	—	—	—	(3,534)	—	(3,534)
Other comprehensive income, net of tax	—	—	—	—	—	—	1	1
Stock compensation	—	—	—	—	216	—	—	216
Equity issuance costs	—	—	—	—	(338)	—	—	(338)
Issuance of stock from RSUs	—	—	12	—	—	—	—	—
Balance September 30, 2023	95,388	$ —	59,538	$ —	$637,053	$(633,876)	$(94)	$ 3,083

	Nine Months Ended September 30, 2023							
	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance December 31, 2023	95,388	$ —	8,955	$ —	$627,936	$(624,187)	$(88)	$ 3,661
Net loss	—	—	—	—	—	(9,689)	—	(9,689)
Other comprehensive income, net of tax	—	—	—	—	—	—	(6)	(6)
Issuance of common stock pursuant to reverse stock split	—	—	318	—	—	—	—	—
Stock compensation	—	—	—	—	656	—	—	656
Common stock purchased	—	—	25,456	—	895	—	—	895
Equity issuance costs	—	—	—	—	(247)	—	—	(247)
Issuance of stock from RSUs	—	—	41	—	—	—	—	—
Exercise of warrants	—	—	24,768	—	7,813	—	—	7,813
Balance September 30, 2023	95,388	$ —	59,538	$ —	$637,053	$(633,876)	$(94)	$ 3,083

See accompanying Notes to Condensed Consolidated Financial Statements.

RESHAPE LIFESCIENCES INC.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(dollars in thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$(5,369)	$ (9,689)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	17	114
Amortization of intangible assets	—	33
Impairment of long-lived assets	—	777
Gain on extinguishment of debt	(429)	—
Gain on disposal of assets, net	—	(33)
Stock-based compensation	169	656
Bad debt expense	61	450
Provision for inventory excess and obsolescence	140	101
Deferred income tax	—	1
Gain on changes in fair value of liability warrants	(46)	(3,850)
Offering cost	—	298
Other noncash items	2	12
Change in operating assets and liabilities:		
Accounts and other receivables	256	(422)
Inventory	667	307
Prepaid expenses and other current assets	119	(329)
Accounts payable and accrued liabilities	673	(2,764)
Warranty liability	—	(182)
Other	—	17
Net cash used in operating activities	(3,740)	(14,503)
Cash flows from investing activities:		
Capital expenditures	—	(43)
Proceeds from sale of capital assets	—	33
Cash used in investing activities:	—	(10)
Cash flows from financing activities:		
Proceeds from sale and issuance of securities	—	12,451
Exercise of warrants	24	—
Payments of equity issuance costs	—	(338)
Net cash provided by financing activities	24	12,113
Effect of currency exchange rate changes on cash and cash equivalents	—	(6)
Net change in cash, cash equivalents and restricted cash	(3,716)	(2,406)
Cash, cash equivalents and restricted cash at beginning of period	4,559	3,955
Cash, cash equivalents and restricted cash at end of period	$ 843	$ 1,549
Supplemental disclosure:		
Cash paid for income taxes	$ 12	$ 2

See accompanying notes to Condensed Consolidated Financial Statements.

RESHAPE LIFESCIENCES INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(dollars in thousands, except per share amounts; unaudited)

(1) Basis of Presentation

The accompanying interim condensed consolidated financial statements and related disclosures of Reshape Lifesciences Inc. (the "Company" or "ReShape") have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") and should be read in conjunction with the consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed on April 1, 2024. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") have been condensed or omitted.

In the opinion of management, the interim consolidated condensed financial statements reflect all adjustments considered necessary for a fair statement of the interim periods. All such adjustments are of a normal, recurring nature. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

Reverse Stock Split

On September 23, 2024, at the commencement of trading, the Company effected a 1-for-58 reverse stock split. Accordingly, all share and per share amounts for the periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split. No fractional shares were issued in connection with the reverse stock split.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 to its audited consolidated financial statements for the year ended December 31, 2023, which are included in the Company's 2023 Annual Report on Form 10-K which was filed with the SEC on April 1, 2024.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may materially differ from these estimates. The Company reviews its estimates on an ongoing basis or as new information becomes available to ensure that these estimates appropriately reflect changes in its business.

Inventory

The Company accounts for inventory at the lower of cost or net realizable value, where net realizable value is based on market prices less costs to sell. The Company establishes inventory reserves for obsolescence based upon specific identification of expired or unusable units with a corresponding provision included in cost of revenue.

Long-Lived Assets

We assess the potential impairment of long-lived assets, principally property and equipment, whenever events or changes in circumstances indicate that the carrying value of the asset group may not be fully recoverable. If an indicator of impairment exists for any of its asset groups, an estimate of undiscounted future cash flows over the life of the primary asset for each asset group is compared to that long-lived asset group's carrying value. If the carrying value of the asset group is greater than the estimated future undiscounted cash flow, the Company then determines the fair value of the assets, and if an asset is

determined to be impaired, the impairment loss is measured by the excess of the carrying amount of the asset over its fair value.

Fair Value of Financial Instruments

The carrying amounts of cash equivalents, accounts receivable, accounts payable and certain accrued and other liabilities approximate fair value due to their short-term maturities. Refer to Note 6 regarding fair value measurements and inputs of warrants.

Net Loss Per Share

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	September 30,	
	2024	2023
Stock options	144	305
Unvested restricted stock units	8	45
Convertible preferred stock	10	10
Warrants	81,432	28,147

Recent Accounting Pronouncements

New accounting standards not yet adopted are discussed below.

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-03, *Income Statement Reporting Comprehensive Income Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires companies to provide more detailed and organized disclosures of their expenses in their income statements. The standard requires breaking down expenses into specific categories, such as employee compensation and costs related to depreciation and amortization. This amendment is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, on a prospective basis and early adoption and retrospective application is permitted. The Company is currently evaluating this new guidance and its impact on its Consolidated Financial Statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)*: Improvements to Income Tax Disclosures, which requires entities to provide additional information in the rate reconciliation and additional disaggregated disclosures about income taxes paid. This guidance requires public entities to disclose in their rate reconciliation table additional categories of information about federal, state, and foreign income taxes and to provide more details about the reconciling items in some categories if the items meet a quantitative threshold. The guidance is effective for annual periods beginning after December 15, 2024. The Company does not expect the adoption of this guidance to impact its consolidated financial statements, but the guidance will impact its income tax disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)*: Improvements to Reportable Segment Disclosures. The amendments require disclosure of significant segment expenses and other segment items and requires entities to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The amendment also requires disclosure of the title and position of the chief operating decision maker ("CODM") and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. This guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application is required, and early adoption is permitted. The Company is currently evaluating the impact the guidance will have on its consolidated financial statements.

(2) Liquidity and Management's Plans

The Company currently does not generate revenue sufficient to offset operating costs and anticipates such shortfalls to continue as the Company has modified its strategy to a metrics-driven approach through a sustainable and scalable business model, via a digital lead generation and re-engagement strategy. As of September 30, 2024, the Company had net working capital of approximately $1.3 million, primarily due to cash and cash equivalents and restricted cash of $0.8 million, and $1.3 million of net accounts receivable. The Company has raised gross proceeds of $0.7 million from the issuance of a senior secured convertible note on October 16, 2024, for further details see Note 11. Based on its available cash resources, the Company will not have sufficient cash on hand to fund its current operations for more than twelve months from the date of this filing. This condition raises substantial doubt about the Company's ability to continue as a going concern.

The Company's anticipated operations include plans to (i) merge with Vyome Therapeutics, Inc and sell certain assets to Biorad, which will continue the operations, (ii) grow sales and operations of the Company with the Lap-Band product line both domestically and internationally as well as to obtain cost savings synergies, (iii) introduce to the market Lap-Band 2.0 FLEX, (iv) continue development of the Diabetes Bloc-Stim Neuromodulation ("DBSN") device, and (v) prior to such merger and sale, explore and capitalize on synergistic opportunities to expand our portfolio and offer future minimally invasive treatments and therapies in the obesity continuum of care. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows, which could include reducing expenditures for marketing and product development activities.

There can be no assurance as to whether the Company will close the planned transactions or whether additional financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, it would have a negative impact on the Company's financial condition and could force the Company to delay, limit, reduce, or terminate product development or future commercialization efforts or grant rights to develop and market product candidates or testing products that the Company would otherwise plan to develop.

Therefore, the plans cannot be deemed probable of being implemented. As a result, the Company's plans do not alleviate substantial doubt about our ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

(3) Supplemental Balance Sheet Information

Components of selected captions in the condensed consolidated balance sheets consisted of the following:

Inventory:

	September 30, 2024	December 31, 2023
Raw materials	$ 965	$1,020
Sub-assemblies	1,163	1,379
Finished goods	806	1,342
Total inventory	$2,934	$3,741

Prepaid expenses and other current assets:

	September 30, 2024	December 31, 2023
Prepaid insurance	$ 95	$110
Professional services	29	—
Patents	5	13
Prepaid advertising and marketing	21	41
Taxes	16	47
Other current assets	51	126
Total prepaid expenses and other current assets	$217	$337

Accrued and other liabilities:

	September 30, 2024	December 31, 2023
Payroll and benefits	$ 702	$ 701
Accrued legal settlements	—	200
Customer deposits	683	639
Taxes	44	61
Accrued professional	169	155
Other liabilities	45	58
Total accrued and other liabilities	$1,643	$1,814

Accounts payable:

During the second quarter of 2024, management requested outside legal counsel to provide guidance with respect to various accounts payables carried on the books from 2020 and prior. Based on the review of the statute of limitations for the various states these vendors were located, legal counsel provided a conclusion regarding whether the laws per the respective states provided that the statute of limitations has expired. The statute of limitations is an affirmative defense in which the defendant introduces evidence, which, if found to be credible, will negate criminal or civil liability, even if it is proven the defendant committed the alleged acts. The party raising the affirmative defense has the burden of proof on establishing that it applies. In a civil action in which a creditor demands payment on a written instrument evidencing a debt, the successful assertion of the statute of limitations defense will bar collection of the debt. In order to assert the statute of limitations as a defense, a defendant must specifically assert the defense is the answer. If a defendant fails to specifically plead the defense, it will be deemed to be waived. Since no action to enforce such liabilities was brought before September 30, 2024, it is our opinion that the liability is time-barred from collection under the respective state laws and should be removed from the Company's balance sheet.

Therefore, the Company made the decision to write-off the payables totaling $429 thousand. As of September 30, 2024, the write-off of $429 thousand resulted in a gain on extinguishment of debt which was reported on the statement of operations for the nine months ended September 30, 2024.

(4) Leases

The Company had a noncancelable operating lease for office and warehouse space in San Clemente, which expired June 30, 2023. On March 13, 2023, the Company entered into a lease for approximately 5,038 square feet of office and warehouse space at 18 Technology Drive, Suite 110, Irvine, California 92618 and relocated its principal executive offices from our former San Clemente, California location to the Irvine, California location. The Irvine lease has a term of 36 months, commencing on May 1, 2023.

The Company does not have any short-term leases or financing lease arrangements. Lease and non-lease components are accounted for separately.

Operating lease costs were $0.1 million and $16 thousand for the three months ended September 30, 2024 and 2023, respectively, and $0.1 million and $0.3 million for the nine months ended September 30, 2024 and 2023, respectively. Variable lease costs were not material.

Supplemental information related to operating leases is as follows:

Balance Sheet information	September 30, 2024	December 31, 2023
Operating lease ROU assets	$177	$250
Operating lease liabilities, current portion	$114	$111
Operating lease liabilities, long-term portion	77	151
Total operating lease liabilities	$191	$262

Cash flow information for the nine months ended September 30,	2024	2023
Cash paid for amounts included in the measurement of operating leases liabilities	$83	$174

Maturities of operating lease liabilities were as follows as of September 30, 2024:

2024 (balance of year)	$ 28
2025	115
2026	59
Total lease payments	202
Less: imputed interest	11
Total lease liabilities	$191
Weighted-average remaining lease term at end of period (in years)	1.9
Weighted-average discount rate at end of period	6.9%

(5) Equity

Common Stock Issued Related to Restricted Stock Units

During the three months ended September 30, 2024 and 2023, the Company issued 3 shares of common stock and 12 shares of common stock, respectively, subject to vesting of the restricted stock units. During the nine months ended September 30, 2024 and 2023, the Company issued 5 shares of common stock and 41 shares of common stock, respectively, subject to vesting of restricted stock units. For further details see Note 9.

May 2024 Exercise of Warrants for Common Stock

On May 30, 2024, an accredited investor exercised outstanding warrants, of which 1,811 shares of common stock were issued in accordance with the terms of the warrant agreement. The Company received approximately $24 thousand of cash.

June 2024 Exercise of Warrants for Common Stock

On June 4, 2024, the Company issued 100,430 shares of common stock in exchange for 185,604 common stock purchase warrants. These warrants were exercised using the cashless mechanism within the warrant agreement.

February 2023 Public Offering of Common Stock and Warrants

On February 8, 2023, the Company closed a public offering of 21,983 units, with each consisting of one share of its common stock, or one pre-funded warrant to purchase one share of its common stock, and one warrant to purchase one and one-half shares of its common stock. Each unit was sold at the public

offering price of $464.00. The warrants in the units are immediately exercisable at a price of $464.00 per share and expire five years from the date of issuance. Alternatively, each warrant can be exercised pursuant to the "alternative cashless exercise" provision, to which the holders would receive an aggregate number of shares of common stock equal the product of (x) the aggregate number of shares of common stock that would be issuable upon a cash exercise and (y) 0.50. For purposes of clarity, one common warrant to purchase one and one-half shares would be exercisable for 0.75 shares under this alternative cashless exercise provision. The shares of common stock (or pre-funded warrants in lieu thereof) and accompanying warrants were only purchasable together in this offering but were issued separately and immediately separable upon issuance. As of September 30, 2024 warrants to purchase 28,869 shares of common stock have been exercised under the alternative cashless exercise for a total of 14,402 shares of common stock.

Net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses, were approximately $10.2 million. The Company has been using the net proceeds of this offering to continue implementation of its growth strategies, for working capital and general corporate purposes.

The Company also granted the underwriters an option to purchase an additional 3,298 shares of common stock and/or additional warrants to purchase up to 4,947 shares of common stock, to cover over-allotments, of which Maxim Group LLC exercised its option to purchase additional warrants to purchase 4,947 shares of common stock.

(6) Warrants

The Company's grants of warrants to purchase common stock are primarily in connection with equity financing. See Note 5 for additional information about equity financings and the related issuance of warrants. Warrant activity for the nine months ended September 30, 2024 is as follows:

	Shares
Balance December 31, 2023	268,937
Issued	—
Exercised	(187,415)
Cancelled	(90)
Balance September 30, 2024	81,432

On February 8, 2023, the Company completed a public offering in which three classes of warrants were issued. There were 37,921 common stock purchase warrants issued with an alternative cashless exercise provision. The alternative cashless exercise allows the holder to exercise one warrant share for 0.5 shares of common stock or exercise via the cash exercise price of $464.00 per share of common stock per warrant. The Company classifies these warrants as a liability, and the Company utilized a bifurcated Black-Scholes option pricing model to consider the cash exercise option and cashless exercise option. The bifurcated Black-Scholes option pricing model used an exercise price where the two exercise methods would be indifferent with market inputs of the stock price on the issuance, risk free interest rate, expected share price volatility and dividend yield. The Company calculates the fair value of the warrants at each reporting period and when a warrant is exercised, with the changes in fair value recognized in the statement of operations.

Below is a summary of the initial inputs used in the bifurcated Black-Scholes option pricing model.

	Cash Exercise	Cashless Exercise
Stock Price	$5.905	$5.905
Exercise Price	$16.00	$ 0.00
Term (years)	5.00	5.00
Volatility	96.50%	96.50%
Risk Free Rate	3.784%	3.784%
Dividend Yield	0%	0%

The following table presents the changes in the fair value of warrant liabilities:

	Common Stock Purchase Warrants
Fair value as of December 31, 2023	$ 72
Gain on changes in fair value of liability warrants	(46)
Fair value as of September 30, 2024	$ 26

In addition, one of the investors purchased 1,552 pre-funded warrants at a price of $463.94 per warrant. These warrants have an exercise price of $0.01 per share and do not expire. The pre-funded warrants were valued at $0.5 million using the fair value approach at the time of issuance. The fair value of the pre-funded warrants was determined using a Black Scholes option pricing model using a risk-free rate of 3.784%, an expected term of 5.0 years, expected dividends of zero and expected volatility of 96.5%.

As part of the terms of the offering, the Company issued 1,265 representative's warrants with an exercise price of $510.40 per share and expiration date on February 3, 2028. The representative's warrants were valued at $0.3 million using the fair value approach at the time of issuance. The fair value of the representative's warrants was determined using a Black Scholes option pricing model using a risk-free rate of 3.786%, an expected term of 4.99 years, expected dividends of zero and expected volatility of 96.5%.

(7) Revenue Disaggregation and Operating Segments

The Company conducts operations worldwide and has sales in the following regions: United States, Australia, Europe and Rest of World. For the three and nine months ended September 30, 2024 and 2023, the Company primarily sold the Lap-Band system and accessories. The following table presents the Company's revenue disaggregated by geography:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
United States	$2,009	$1,732	$5,290	$5,473
Australia	111	139	316	419
Europe	168	258	564	756
Rest of World	4	26	31	48
Total revenue	$2,292	$2,155	$6,201	$6,696

Operating Segments

The Company conducts operations worldwide and is managed in the following geographical regions: United States, Australia, Europe and the Rest of World (primarily in the Middle East). All regions sell the Lap-Band system, which consisted of nearly all our revenue and gross profit for the three and nine months ended September 30, 2024 and 2023. There was no revenue or gross profit recorded for the DBSN device for the three and nine months ended September 30, 2024 and 2023, as this product is still in the development stage. Additionally, there was no revenue recorded for the Obalon Balloon system during the three months and nine months ended September 30, 2024 and 2023.

(8) Income Taxes

During the three months ended September 30, 2024 and 2023, the Company recorded income tax expense of $6 thousand and $3 thousand, respectively. During the nine months ended September 30, 2024 and 2023, the Company recorded income tax expense of $34 thousand and $21 thousand, respectively. The income tax expense is related to minimum state taxes and projected Australian and Netherlands income, respectively. The income tax provisions for the three and nine months ended September 30, 2024 were calculated using the discrete year-to-date method. The effective tax rate differs from the statutory tax rate of 21% primarily due to the existence of valuation allowances against net deferred tax assets and current liabilities resulting from the estimated state income tax liabilities and foreign tax liabilities.

In assessing the realization of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Based on the level of historical losses, projections of losses in future periods and potential limitations pursuant to changes in ownership under Internal Revenue Code Section 382, the Company provided a full valuation allowance at both September 30, 2024 and December 31, 2023.

(9) Stock-based Compensation

Stock-based compensation expense related to stock options and RSUs issued under the ReShape Lifesciences Inc. 2022 Stock Incentive Plan (the "Plan") for the three months and nine months ended September 30, 2024 and 2023 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Sales and marketing	$ 4	$ 30	$ 19	$ 89
General and administrative	13	128	83	384
Research and development	15	58	67	183
Total stock-based compensation expense	$32	$216	$169	$656

Stock Options

A summary of the status of the Company's stock options as of September 30, 2024, and changes during the nine months ended September 30, 2024, are as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	263	$21,909.50		$ —
Options granted	—	—		
Options exercised	—	—		
Options cancelled	(105)	7,629.90		
Outstanding at September 30, 2024	158	$31,381.48	6.10	$ —
Exercisable at September 30, 2024	144	$34,101.10	5.97	$ —
Vested and expected to vest at September 30, 2024	158	$31,381.48	6.10	$ —

There was no intrinsic value to outstanding stock options at September 30, 2024. The unrecognized share-based expense at September 30, 2024 was $34 thousand and will be recognized over a weighted average period of 1.05 years.

Stock option awards outstanding under the Company's incentive plans have been granted at exercise prices that are equal to the market value of its common stock on the date of grant. Such options generally vest over a period of four years and expire at ten years after the grant date. The Company recognized compensation expense ratably over the vesting period. The Company uses a Black-Scholes option-pricing model to estimate the fair value of stock options granted, which requires the input of both subjective and objective assumptions as follows:

Expected Term — The estimate of expected term is based on the historical exercise behavior of grantees, as well as the contractual life of the options granted.

Expected Volatility — The expected volatility factor is based on the volatility of the Company's common stock for a period equal to the term of the stock options.

Risk-free Interest Rate — The risk-free interest rate is determined using the implied yield for a traded zero-coupon U.S. Treasury bond with a term equal to the expected term of the stock options.

Expected Dividend Yield — The expected dividend yield is based on the Company's historical practice of paying dividends on its common stock.

Restricted Stock Units

A summary of the Company's unvested RSUs award activity for the nine months ended September 30, 2024, is as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested RSUs at December 31, 2023	25	$ 7,505.04
Granted	—	—
Vested[(1)]	(17)	$(9,333.94)
Cancelled/Forfeited	—	—
Non-vested RSUs at September 30, 2024	8	$ 3,847.14

(1) At September 30, 2024, there were 2 shares of common stock related to RSU awards that had vested and the shares were not distributed to the participants.

The fair value of each RSU is the closing stock price on the Nasdaq of the Company's common stock on the date of grant. Upon vesting, a portion of the RSU award may be withheld to satisfy the statutory income tax withholding obligation. The remaining RSUs will be settled in shares of the Company's common stock after the vesting period. The unrecognized compensation cost related to the RSUs at September 30, 2024 was $25 thousand and expected to be recognized over a period of 0.92 years.

(10) Commitment and Contingencies

Litigation

On August 6, 2021, Cowen and Company, LLC filed a complaint against ReShape, as successor in interest to Obalon Therapeutics, in the Supreme Court of the State of New York based on an alleged breach of contract arising out of Cowen's prior engagement as Obalon's financial advisor. The complaint alleges that Cowen is entitled to be paid a $1.35 million fee in connection with ReShape's merger with Obalon under the terms of Cowen's engagement agreement with Obalon. The complaint also sought reimbursement of Cowen's attorneys' fees and interest in connection with its claim. On May 11, 2023, the Supreme Court of the State of New York issued the final judgement in favor of Cowen & Company in the amount of $1.35 million, plus interest at the statutory rate of 9% per annum from June 16, 2021 until judgement is paid in full, and reimbursement of $675,000 of Cowen's attorneys' fees, with $275,000 to be paid upfront, $200,000 paid after six months and $200,000 paid after 12 months. As of September 30, 2024, the Company has paid the judgement, interest and legal fees in full.

The Company is not aware of any pending or threatened litigation against it that could have a material adverse effect on the Company's business, operating results or financial condition, other than what was disclosed above. The medical device industry in which the Company operates is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, the Company may be involved in various legal proceedings from time to time.

Product Liability Claims

The Company is exposed to product liability claims that are inherent in the testing, production, marketing, and sale of medical devices. Management believes any losses that may occur from these matters

are adequately covered by insurance, and the ultimate outcome of these matters will not have a material effect on the Company's financial position or results of operations. The Company is not currently a party to any product liability litigation and is not aware of any pending or threatened product liability litigation that is reasonably possible to have a material adverse effect on the Company's business, operating results or financial condition.

(11) Subsequent Events

In a private transaction, on October 16, 2024, the Company entered into a securities purchase agreement (the "SPA") with an institutional investor (the "Investor"). Pursuant to the SPA, the Company agreed to issue the Investor a senior secured convertible note in the aggregate original principal amount of $833,333.34 (the "Note"), and also issue to the Investor 7,983 shares of common stock, par value $0.001, of the Company ("Common Stock") as "commitment shares" to the Investor.

The Company is the issuer of the Note, and its respective subsidiaries will guaranty the obligations under the Note pursuant to a Guaranty, dated October 16, 2024 (the "Guaranty"). The Note is fully secured by collateral of the Company and its subsidiaries. The security interest in favor of the Investor, as collateral agent, covers substantially all assets of the Company including, without limitation, the intellectual property, trademark, and patent rights of the Company. The parties entered into a Security Agreement (the "Security Agreement") and certain intellectual property security agreements granting such security interest in favor of the Investor.

In connection with the SPA, the Company issued to the Investor the Note on October 16, 2024, which bears an interest rate of 10% per annum and is due and payable on the earlier of (i) January 16, 2025 and (ii) the date of consummation or termination of the Company's previously announced merger with Vyome Therapeutics, Inc. The initial conversion price of the Note is $5.22 per share of Common Stock. The Note may not be converted by the Investor into shares of Common Stock if such conversion would result in the Investor and its affiliates owning in excess of 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of all shares issuable upon conversion of the Note. The Note provides for certain events of default that are typical for a transaction of this type, including, among other things, any breach of the representations or warranties made by the Company or its subsidiaries. In connection with any event of default that results in the acceleration of payment of the Note and while it is continuing, the interest rate on the Note shall accrue at an interest rate equal to the lesser of 24% per annum or the maximum rate permitted under applicable law.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Vyome Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vyome Therapeutics Inc. (the "Company") as of December 31, 2023 and 2022 and the consolidated statements of operations and comprehensive loss, changes in stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered continued negative cash flows and losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Kreit and Chiu CPA LLP

We have served as Vyome Therapeutics Inc.'s auditor since 2023.

New York, New York
June 18, 2024

VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

(Amounts in USD)	Dec 31, 2023	Dec 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 16,647	$ 458,244
Accounts receivable, net	66.816	122
Other current assets	86,363	72,845
Total current assets	**169,826**	**531,211**
Non-current assets		
Property and equipment, net	85,932	107,326
Intangible asset – shell company	314,191	314,191
Goods and service tax and other credits receivable	697,827	734,372
Deferred offering costs	66,415	66,415
Right-of-use of asset, net	87,060	35,900
Total non-current assets	**1,251,425**	**1,258,204**
Total assets	**$ 1,421,251**	**$ 1,789,415**
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable and accrued expenses	$ 910,537	$ 937,245
Liabilities to be settled in equity	1,680,210	1,680,210
Due to affiliates	452,432	377,651
Operating lease liability – current portion	25,037	42,665
Salary and post-employment benefits payable	1,375,706	1,171,423
Other current liability	69,589	113,104
Convertible debt – current portion	1,963,386	583,510
Total current liabilities	**$ 6,476,897**	**$ 4,905,808**
Non-current liabilities		
Convertible debt – net of current portion	$ 967,503	$ 2,248,695
Operating lease liability – net of current portion	62,023	—
Total non-current liabilities	**1,029,526**	**2,248,695**
Total liabilities	**$ 7,506,423**	**$ 7,154,503**
Commitments and contingencies		
Stockholders' deficit		
Common stock, 20,000,000 shares authorized, par value of $0.001, 1,893,120 shares issued and outstanding at December 31, 2023 and 2022	$ 1,892	$ 1,892
Preferred stock, 15,000,000 shares authorized, par value of $0.001, 14,759,760 shares issued and outstanding at December 31, 2023 and 2022	46,984,875	46,984,875
Additional paid-in capital	643,709	643,709
Accumulated deficit	(53,927,896)	(53,207,976)
Accumulated other comprehensive income	212,248	212,412
Total stockholders' deficit	**$ (6,085,172)**	**$ (5,365,088)**
Total liabilities and stockholders' deficit	**$ 1,421,251**	**$ 1,789,415**

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS FOR THE YEARS ENDED DECEMBER 31,

(Amounts in USD)	2023	2022
Revenue		
Revenue	$ 415,940	$ 382,865
Cost of goods sold	(133,408)	(236,746)
Gross profit	**$ 282,532**	**$ 146,119**
Operating expenses		
Selling, general and administrative	$ 755,805	$ 826,602
Research and development	294,445	423,700
Total operating expenses	**$1,050,250**	**$ 1,250,302**
Loss from Operations	(767,718)	(1,104,183)
Interest expenses	(164,680)	(124,981)
Other income(loss), net	(1,581)	122,290
Fair value adjustment	214,059	(148,424)
Total other income(expense), net	**47,798**	**(151,115)**
Net loss	**$ (719,920)**	**$(1,255,298)**
Other comprehensive loss, net of tax		
Foreign currency translation adjustments	(450)	(13,518)
Other comprehensive loss, net of tax	**(450)**	**(13,518)**
Total comprehensive loss	**$ (720,370)**	**$(1,268,816)**
Net loss per share:		
Basic and diluted	**$ (0.38)**	**$ (0.67)**
Weighted average number of shares:		
Basic and diluted	1,893,120	1,893,120

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIT

For the years ended December 31, 2023 and December 31, 2022

(Amounts in USD)	Common stock		Preferred stock		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income (Loss)	Total Stockholders Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	1,893,120	$1,892	14,759,760	$46,984,875	$618,697	$(51,952,678)	$212,205	$(4,135,009)
Stock-based compensation					25,012			25,012
Net loss						(1,255,298)		(1,255,298)
Foreign currency translation adjustments							207	207
Balance at December 31, 2022	1,893,120	$1,892	14,759,760	$46,984,875	$643,709	$(53,207,976)	$212,412	$(5,365,088)
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(719,920)	—	(719,920)
Foreign currency translation adjustments	—	—	—	—	—	—	(164)	(164)
Balance at December 31, 2023	1,893,120	1,892	14,759,760	46,984,875	643,709	(53,927,896)	212,248	(6,085,172)

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	(Amounts in USD)	
	2023	**2022**
Cash flows from operating activities		
Net loss	**$ (719,920)**	**$(1,255,298)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21,193	56,148
Stock-based compensation	—	25,012
(Gain) loss on fair value adjustment of convertible debt	(214,059)	148,424
Non-cash accrued interest expense	162,741	122,933
Changes in operating assets and liabilities:		
Accounts receivables, net	$ (66,694)	$ (76)
Inventories, net	—	22,605
Prepaid expenses and other current assets	(13,518)	205,945
Other assets	(14,615)	(36,689)
Accounts payable & accrued expenses	(26,708)	104,209
Due to Affiliates	102,432	100,000
Post employment benefits	204,283	211,433
Other Liabilities	882	(67,526)
Net cash used in operating activities	**$ (563,983)**	**$ (362,879)**
Cash flows provided from investing activities:		
Proceeds from sale of fixed assets	201	68
Net cash provided from investing activities	**$ 201**	**$ 68**
Cash flows from financing activities:		
Proceeds from convertible debt	150,000	725,000
Advance from Affiliates	(27,651)	27,651
Net cash provided by financing activities	**122,349**	**752,651**
Effect of exchange rate changes on cash and cash equivalents	(164)	208
Net (Decrease)/Increase in cash and cash equivalents	(441,597)	390,047
Cash and cash equivalents at beginning of the year	458,244	68,197
Cash and cash equivalents at end of the year	**$ 16,647**	**$ 458,244**
Supplemental disclosure of cash flow information		
Cash paid for interest expenses	—	—
Cash paid for income tax expenses	—	—
Supplemental schedule of non-cash investing and financing activities		
Reclassification of accounts payable to liabilities to be settled in equity	$1,680,210	$ 1,680,210

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts are in US Dollars except per share data and as stated otherwise)

1. Organization and principal activities

Business:

Vyome Therapeutics, Inc. ("VTI"), a Delaware corporation, was incorporated on August 22, 2017. VTI was formed with the intent of operating the R&D business of Vyome Biosciences India Private Limited, India (the "R&D Business"), which was transferred to Vyome Therapeutics Limited (a wholly owned subsidiary of VTI) pursuant to a Demerged order of National Company law Tribunal ("NCLT") in India, formally consummated in December 2018. VTI and the wholly owned subsidiary in India, Vyome Therapeutics Limited ("VTL") are collectively referred to as the "Company" or "Vyome". "R&D business" is defined as novel drug development in the area of immune-inflammatory diseases space and the commercial exploitation of the same.

The Company is a Princeton, NJ based clinical stage specialty pharmaceutical company working to treat immune-inflammatory and rare diseases of unmet need with next generation therapeutic solutions. The lead program VT-1953, a topical gel with a novel molecule to treat signs and symptoms of Malignant Fungating wounds, a potentially orphan drug program. The Company is planning to have discussions with Food & Drug Administration (FDA) on pivotal trial protocol in third quarter of 2024. The Company also has Pre-Investigative New Drug application stage ophthalmic drops program, a potentially orphan drug program, a repurposed immune modulator to treat steroid sparing anterior uveitis. Another late clinical stage program, VB 1953, for moderate to severe acne has successfully completed its Phase II clinical trial and this program is Phase 3 ready. The Company may experience delays in the conduct of clinical trials of its candidates. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Any delays in completing the Company's clinical trials will increase its costs, slow down its product development, timeliness and approval process and delay its ability to generate revenue.

The Company also is developing other assets for treating immune-inflammatory diseases which are in pre-clinical or early clinical development.

The Company also has commercialized novel reformulated topical anti-fungal products in India after two such products successfully completing clinical testing in India. The Company has entered into licensing and a marketing agreement with Sun Pharma group of companies to sell a family of novel topical anti-fungal products owned by the Company in India. The Company uses third party entities to manufacture the products.

Since its inception, the Company has devoted substantially all its efforts to drug development, business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of pre-clinical studies, clinical studies and clinical trials, the need to obtain marketing approval for its drug candidates and its consumer products, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to transition from pilot scale manufacturing to large scale production.

2. Summary of Significant Accounting Policies

a) Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and pursuant to the accounting

and disclosure rules and regulations of the Securities and Exchange Commission ("SEC"), and reflect all adjustments consisting only of normal recurring adjustments of the Company, which are, in opinion of management, necessary for a fair presentation of the financial position as of December 31, 2023 and 2022, and the results of operations, and cash flows for the years presented. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

The Company organized its operations into two operating segments. The segments reflect the way the Company evaluates its business performance and manages its operations by the Company's chief operating decision maker ("CODM") for making decisions, allocating resources and assessing performance. The Company's CODM has been identified as the chief executive officer. The Company determined it has in two operating segments: (1) Sale of Products and (2) biotechnology segment. The Company's reportable segments are strategic business units that offer different products and services. They are managed separately because each business requires different technology and marketing strategies.

As the Company's long-lived assets, except for the intangible asset and deferred offering costs are substantially all located in India and all of the Company's revenue and expense related to the sale of products are derived from within India, no geographical segments are presented.

The Company operates in two segments — Sale of products and biotechnology activities — see Note 14.

b) Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, VTL. All intercompany accounts and transactions have been eliminated in the consolidation.

c) Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. For the years ended December 31, 2023 and 2022, the Company has generated a net loss of $719,920 and $ 1,255,298 respectively. At December 31, 2023, the Company's current liabilities exceed its current assets by approximately $6.1 million. The Company's major sources of funds to date have been through the sale of preferred stock and the issuance of convertible debt. The Company does not believe it has sufficient funds to finance the operating requirements for at least the next 12 months from the issuance date of these consolidated financial statements. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Obtaining additional financing to support the successful development of the Company's contemplated plan of drug development and operations, and its transition, ultimately, to the attainment of profitable operations are necessary for the Company to continue operations. The Company may raise additional funding from its current set of investors. In addition, a financial advisor has been engaged to pursue additional capital funding or other strategic transactions and the Company will continue to seek funds through debt or equity financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources of financing. However, there can be no assurances that such financing or other strategic transactions will be available on acceptable terms, or at all. If the Company is unable to raise additional funds, it will need to do one or more of the following:

- Delay clinical trials and processes;
- License third parties to develop and commercialize products or technologies that it would otherwise seek to develop and commercialize itself;
- Seek strategic alliances or business combinations;
- Attempt to sell the Company;

- Cease operations; or
- Declare bankruptcy

The Company continues to raise additional capital through the issuance of convertible notes. The Company is in discussions with investment bankers to raise additional capital in the public or private markets. There is no assurance that such financing can be completed. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is implementing plans to reduce expenses and seek additional financing. However, there can be no assurance that these plans will be successful. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The consolidated financial statements do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

d) Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results, as determined at a later date, could differ from those estimates. Significant estimates used in preparing these audited consolidated financial statements include realization of deferred tax assets, timing of the recognition of research and development costs, fair value of debt and equity-based instruments, and future obligations under employee benefit plans.

e) Foreign Currency Translation and Transactions

The Company also operates in India, which may give rise to significant foreign currency risks from fluctuations and the degree of volatility of foreign exchange rates between the US dollar and the Indian Rupee.

The Company's functional currency is the United States Dollar. The functional currency of its Indian subsidiary is Indian National Rupees. Consequently, revenues and expenses of operations of the Indian subsidiary are translated into United States Dollars using average period exchange rates, while assets and liabilities of the Indian subsidiary are translated into United States Dollars using the year-end exchange rate in effect at the balance sheet dates. Adjustments resulting from the translation of functional currency financial statements to reporting currency are accumulated and reported as a part of Accumulated Other Comprehensive Income, a separate component of stockholders' equity in the accompanying consolidated balance sheets.

Transactions in foreign currencies are translated at the exchange rate prevailing on the date of the transaction. Resulting gains or losses from settlement of such foreign currency transactions are included in the consolidated statements of operations. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates in effect on the balance sheet date. Non-Monetary assets and liabilities denominated in foreign currencies are expressed in functional currency at the historical exchange rates. Losses resulting from foreign currency transactions amounting to $ 450 and $ 13,518 for the years ended December 31, 2023 and 2022 respectively are included in the consolidated statements of operations under the caption selling, general and administrative expenses.

f) Cash and Cash Equivalents

Cash includes all highly liquid instruments with a maturity of three months or less, when purchased. The Company maintains its cash balances in financial institutions which are insured by the Federal Deposit Insurance Corporation ("FDIC"). At various times during the year, such balances may exceed the FDIC limit. The Company has not experienced any credit losses associated with its balances in

such accounts for the years ended December 31, 2023 and 2022. Cash held in the U.S. bank account as of December 31, 2023 and December 31, 2022 was approximately $ 5,521 and $ 434,324, respectively. Cash held in India as of December 31, 2023 and December 31, 2022 was approximately $11,126 and $23,920 respectively.

g) Accounts Receivable, net

The Company records trade accounts receivable at net realizable value and are included in other current assets on the accompanying consolidated balance sheet. Generally, the Company does not require collateral to support its accounts receivable. Outstanding accounts receivable balances are reviewed periodically, and reserves are provided at such a time that management believes it is probable that such balances will not be collected within a reasonable period of time. Management determined that no allowance for doubtful accounts was necessary as of December 31, 2023, or 2022. Accounts Receivable is grouped in other current assets in the Consolidated Balance Sheets.

In 2023 the Company adopted *Financial Instruments — Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instrument*s, which removed all current thresholds and requires entities under the new current expected credit loss ("CECL") model to recognize an allowance for credit losses for the difference between the amortized cost basis of a financial instrument and the amount of amortized cost that an entity expects to collect over the instrument's contractual life. The new CECL model is based upon expected losses rather than incurred losses. The adoption of ASU 2016-13 did not have a material impact on the consolidated financial on our financial statements. Management determined that no allowance for doubtful accounts was necessary as of December 31, 2023, or 2022.

h) Inventories

Inventories are valued at lower of cost and net realizable value, including necessary provision for obsolescence. Cost is determined using the last-in, first-out method. As a result of the change in our relationship with our major customer (see Note 14), we do not carry inventory as of December 31, 2023, and do not expect to into the future.

i) Property and equipment, net

Property and equipment, net is stated at net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, summarized as follows:

Computers and software	3 years
Office equipment	5 years
Furniture and Fixtures	10 years
Lab machinery	10 years
Leasehold improvements	Lower of estimated useful life or remaining period of lease term

Repairs and maintenance costs are expensed as incurred; major renewals and betterments are capitalized. When assets are disposed of, the assets and related allowances for depreciation and amortization are eliminated from the accounts and any resulting gain or loss is reflected in operations.

j) Goods and Service Tax and Other Credits Receivable

The Company has indirect tax credit carryforwards arising in India, which may be utilized or refunded as VTL generates sales to third parties or invoices to VTI pursuant to intercompany transfer pricing arrangements. The Company expects to utilize these indirect tax credit carryforwards over a 4-to-5-year period.

k) Intangible Assets

On August 21, 2021, Vyome acquired the majority of the outstanding shares (purchase of substantially all of the outstanding shares of preferred stock) of Livechain, Inc., ("LICH") for

$220,000. Total costs of the asset acquisition were $314,191. LICH is an inactive non-reporting shell ("Shell Company") that trades on the bulletin board under the ticker symbol LICH. As of the date of the transaction and through December 31, 2023, LICH had no operations. LICH did not meet the definition of a business and therefore was accounted for as an asset acquisition of the shell company, a single indefinite-lived asset.

Intangible assets with indefinite lives (i.e., non-reporting shell) are not amortized; rather, they are tested for impairment whenever events or circumstances exist that would make it more likely than not that an impairment exists.

l) Impairment of Long-Lived Assets

The Company evaluates all long-lived assets for impairment annually, or sooner if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If the carrying amount is not fully recoverable, an impairment loss is recognized to reduce the carrying amount to fair value and is charged to expense in the period of impairment. As of December 31, 2023 and 2022 management has determined that these assets are not impaired.

m) Revenue Recognition

The Company recognizes revenue under ASC Topic 606, "*Revenue from Contracts with Customers*" ("ASC 606"). The Company determines revenue recognition through the following steps:

- Step 1: Identify the contract with the customer;
- Step 2: Identify the performance obligations in the contract;
- Step 3: Determine the transaction price;
- Step 4: Allocate the transaction price to the performance obligations in the contract; and
- Step 5: Recognize revenue when the company satisfies a performance obligation.

The Company records sales of its dermatological products to the pharmaceutical company when performance obligations with customers are satisfied. The Company's performance obligation is a promise to transfer a distinct good to the customer and each distinct good represents a single performance obligation. Such performance obligations are satisfied at a point in time and revenues are recognized when all rights and rewards of ownership are transferred. The majority of the Company's products are shipped by common carriers resulting in recognition of revenues upon shipment at which time control passes to the customer. Revenue is measured at the amount of consideration the Company expects to receive in exchange for the transferring of products. Customers may be entitled to cash discounts, typically denoted at the time of invoicing and shipping. Such amounts are considered to be variable consideration under ASC 606. An estimate for cash discounts is included in the transaction price as a component of sales and is estimated based on the satisfaction of outstanding receivables and historical performance. The Company does not have any material financing terms as payment is received shortly after the transfer of control of the products to the customer within a period of 30-60 days.

Pursuant to licensing and marketing contracts, the Company receives payments from its pharmaceutical company marketing partner for the right to distribute the products ("royalties"). Such royalty payments are linked to the net sales value of the products by its marketing partner to third parties and are recognized in the period to which the royalty relates. Such amounts are recorded under Revenue from operations in the Consolidated Statements of Operation and Comprehensive Loss.

The Company recognizes milestone payments under the license and marketing agreements when all performance obligations related to the identified performance obligations are completed.

n) Cost of products sold

The cost of products sold represents the cost of manufacturing the products supplied by third party manufacturers.

o) Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include employee compensation and overheads. External expenses include development, clinical trials, statistical analysis and report writing and regulatory compliance costs incurred with clinical research organizations and other third-party vendors. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs. Payments made to third parties that perform research and development services on the Company's behalf are expensed as services are rendered, or as contractually agreed.

p) Stock-based Compensation

The Company accounts for stock options granted to employees and non-employees at fair value, which is measured using the Black-Scholes Option pricing model. The fair value measurement date for employee awards is the date of grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grant, generally equal to the vesting period and uses the straight-line method to recognize stock-based compensation.

The Company's policy is to account for forfeitures of awards when they occur in accordance with ASC 718, *Compensation — Stock Compensation*. The Company reverses compensation cost previously recognized, in the period the award is forfeited, for an award that is forfeited before completion of the requisite service period.

The Company utilizes the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value options granted. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying stock issuable upon exercise of the options, expected life of the options, risk-free interest rate, expected dividend yield and expected volatility from peer public companies of the price of the underlying stock.

As the Company's common stock has not been publicly traded, its board of directors periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its common stock prepared by an independent valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The expected life of the stock options in years is estimated using the "simplified method," as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, as the Company has no historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected life of the option. The expected dividend yield is zero as the Company has no history of paying dividends and no plans to do so in the near term.

q) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards in the consolidated financial statement. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in unaudited consolidated statements of operations in the period that includes the enactment date.

Valuation allowances are recognized to reduce deferred tax assets to the amount that will more likely than not be realized. In assessing the need for a valuation allowance, management considers all available evidence for each jurisdiction including past operating results, estimates of future taxable income and the feasibility of ongoing tax planning strategies. When the Company changes its determination as to the amount of deferred tax assets that can be realized, the valuation allowance is adjusted with a corresponding impact to income tax expense in the period in which such determination is made.

The Company also accounts for uncertain tax positions in accordance with ASC Topic 740, *Income Taxes*. This guidance prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. As of December 31, 2023 and 2022, the Company had no uncertain tax positions which affected its financial position and its results of operations or its cash flows and will continue to evaluate for uncertain tax positions in the future. There are no interest costs or penalties provided for in the Company's consolidated financial statements for the years ended December 31, 2023 and 2022. If at any time the Company should record interest and penalties in connection with income taxes, the interest and the penalties will be expensed within the general and administrative expenses category in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

r) Leases

The Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 842, "Leases", establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. Lessor accounting under the new standard is substantially unchanged. Additional qualitative and quantitative disclosures are also required.

The Company adopted the following practical expedients and accounting policies elections related to this standard:

- Short-term lease accounting policy election allowing lessees to not recognize ROU assets and liabilities for leases with a term of 12 months or less; option to not separate lease and non-lease components in the Company's lease contracts; and
- The package of practical expedients applied to all of its leases, including (i) not reassessing whether any expired or existing contracts are or contain leases, (ii) not reassessing the lease classification for any expired or existing leases, and (iii) not reassessing the capitalization of initial direct costs for any existing leases.

Disclosures related to the amount, timing and uncertainty of cash flows arising from leases are included in Note 12.

s) Notes Payable

The Company has elected to account for notes payable to a shareholder using the fair value option in accordance with the guidance contained in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 825-10-25. The fair value option provides an option to elect fair value as an alternative measurement for selected financial assets, financial liabilities, unrecognized firm commitments, and written loan commitments. See Note 8 for additional information. The Company adopted ASU 2020-06 effective December 31, 2021. ASC 815-40-65-1(d) also allows a reporting entity to make a one-time irrevocable election to apply the fair value option in ASC 825-10 as of the date of adoption for any liability classified convertible securities that are within the scope of ASC 825-10. The impact of electing the fair value option would be reflected through a cumulative effect adjustment to the opening retained earnings balance as of the beginning of the first reporting period a reporting entity adopted ASU 2020-06. However, since the Company had previously adopted the fair value option for its convertible debt, there was no impact on the adoption of ASU 2020-06.

t) Fair Value Measurements

The Company considers its cash and cash equivalents, accounts receivable, and accounts payable to meet the definition of financial instruments, and the carrying amounts of such instruments approximated their fair values due to the short maturities of these instruments. The Company records the convertible debt at fair value.

The Company measures fair value as required by the ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, there exists a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2 — Inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

Level 3 — Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date.

The Company utilizes a Probability Weighted Expected Return Model ("PWERM") to value the convertible debt. The quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's convertible debt that are categorized within Level 3 of the fair value hierarchy included the discount rate and expected financing date. The other factors used in the calculation of fair value are contractual terms of the convertible note instruments.

The following table sets forth the financial assets, measured at fair value, by level within the fair value hierarchy as at December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Level 3		
Convertible debt	$2,930,889	$2,832,205

u) Basic and diluted net loss per common share

Net loss per share information is determined using the two-class method, which includes the weighted-average number of shares of common stock outstanding during the period and other securities that participate in dividends (a "participating security"). The Company considered its Preferred Stock to be participating securities because the shares included rights to participate in dividends with the common stock.

Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. The net loss attributable to common stockholders is calculated by adjusting the net loss of the Company for the accretion on the Preferred Stock. Net losses are not allocated to preferred stockholders as they do not have an obligation to share in the Company's net losses. In periods with net income attributable to common stockholders, the Company would allocate net income first to preferred stockholders based on dividend rights under the Company's certificate of incorporation and then to preferred and common stockholders based on

ownership interests. Diluted net loss per share attributable to common stockholders is computed using the more dilutive of (1) the two-class method or (2) the if-converted method.

During the years ended December 31, 2023 and 2022, diluted earnings per common share is the same as basic earnings per common share because, as the Company incurred a net loss during each period presented, the potentially dilutive securities from the assumed exercise of all outstanding stock options would have an anti-dilutive effect. The diluted shares as of December 31, 2022 not included in the loss per share calculation include 14,759,760 shares of common stock issuable upon conversion of preferred stock and 1,101,600 shares potentially issuable under stock options. The diluted shares as of December 31, 2023 not included in the loss per share calculation include 14,759,760 shares of common stock issuable upon conversion of preferred stock and 812,720 shares potentially issuable under stock options.

v) Post Employment benefits

The Subsidiary in India has a defined benefit gratuity scheme for its employees in India. This gratuity scheme provides for lump sum payment in accordance with the provisions of Payment of Gratuity Act, 1972 to vested employees at retirement or death while in employment or on termination of employment of an amount equivalent to 15 days basic salary payable for each completed year of service or part thereof in excess of six months subject to a limit of INR1,000,000 (equivalent to approximately $ 12,000). Vesting occurs upon completion of 5 years of continuous service.

Accumulated Compensated absences, which are expected to be encashed within 12 months from end of the year, are treated as short term employee benefits. The obligation towards the same is measured at the expected cost of accumulating compensated absences as the additional amount expected to be paid as a result of the unused entitlement at the end of the year. Actuarial gains or losses are recognized in the Consolidated Statement of Operations and Comprehensive Loss in the year in which they arise.

w) Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB, and are early adopted by the Company or adopted as of the specified effective date. There were no recent accounting pronouncements that impacted the Company or are expected to have a significant effect on its consolidated financial statements.

3. Other current assets

Other current assets consist of the following:

	At December 31 2023	At December 31 2022
Advances to suppliers	$ —	$32,154
Others	86,363	40,691
Total	**$86,363**	**$72,845**

4. Property and equipment, net

Property and equipment, net consist of the following:

	At December 31 2023	At December 31 2022
Buildings and Improvement	$ 160,458	$ 160,458
Computer and office equipment	85,449	85,449
Furniture & fixtures	13,471	13,832
Laboratory equipment	488,753	488,753
Total	748,131	748,492
Accumulated depreciation	(662,199)	(641,166)
Net fixed assets	**$ 85,932**	**$ 107,326**

Depreciation expense is included in selling, general and administrative expense in the accompanying Consolidated Statements of Operations and Comprehensive Loss and was $ 21,193 and $ 56,148 for the years ended December 31, 2023 and 2022 respectively.

5. Goods and service tax and other credits receivable

The Company's balance of goods and service tax and other credits receivable from government authorities as of December 31, 2023 and 2022 consist of the following:

	December 31, 2023	December 31, 2022
Tax deducted at source and tax collected at source receivable	$ 14,158	$ 8,112
Goods and service tax refund receivable	4,736	—
Input goods and service tax credit	678,933	726,260
	$697,827	$734,372

6. Accounts payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2023 and 2022 consist of the following:

	December 31, 2023	December 31, 2022
Accounts payable	$589,839	$586,310
Accrued expenses	320,698	350,935
	$910,537	**$937,245**

7. Salary and post-employment benefits payable

Salary and post-employment benefits payable as of December 31, 2023 and 2022 consist of the following:

	December 31, 2023	December 31, 2022
Salaries payable	$1,211,205	$1,009,475
Accrued leave encashment (note 12)	84,647	83,724
Accrued gratuity plan (note 12)	79,854	78,224
	$1,375,706	**$1,171,423**

8. Convertible debt

Commencing in October 2020, the Company began raising money under a compulsorily convertible promissory note (the "Promissory Notes") pursuant to a Subscription Agreement (the "Subscription Agreement"). The Promissory Note was issued as part of a private placement (the "Offering") for the sale up to $2,132,000 (which was subsequently expanded) of secured convertible promissory notes (collectively, the "Promissory Notes") for a period until three years of maturity. The Promissory Notes bear interest at a rate of eight percent (8%) per annum, on a non-compounding basis, and are due and payable on the earlier of (i) the date upon which the Promissory Notes are converted into equity securities of the Company, or (ii) at maturity in three (3) years ("Maturity Date").

a) In the event that the Company issues and sells shares of its equity securities ("**Equity Securities**") to investors (the "**Investors**") prior to the Maturity Date in an equity financing with total proceeds to the Company of not less than $10,000,000 (excluding the conversion of the Promissory Notes or other convertible securities issued for capital raising purposes (*e.g.*, Simple Agreements for Future Equity) (a "**Qualified Financing**"), then the outstanding principal amount of this Note and any unpaid accrued interest shall automatically convert in whole without any further action by the Holder into Equity Securities sold in the

Qualified Financing at a conversion price equal to the cash price per share paid for Equity Securities by the Investors in the Qualified Financing multiplied by 0.75 in some notes or 0.8 in some other notes; provided, that if such Qualified Financing is also a Deemed Liquidation Event (as defined in the Company's Certificate of Incorporation, as amended, restated, and otherwise in effect from time to time, the "**Certificate of Incorporation**"), shall govern with respect to the conversion of this Note. The issuance of Equity Securities pursuant to the conversion of this Note shall be upon and subject to the same terms and conditions applicable to Equity Securities sold in the Qualified Financing. Notwithstanding this paragraph, if the conversion price of the Notes as determined pursuant to this paragraph (the "**Conversion Price**") is less than the price per share at which Equity Securities are issued in the Qualified Financing, the Company may, solely at its option, elect to convert this note into shares of a newly created series of preferred stock having the identical rights, privileges, preferences and restrictions as Equity Securities issued in the Qualified Financing, and otherwise on the same terms and conditions, other than with respect to (if applicable): (i) the per share liquidation preference and the conversion price for purposes of price-based anti-dilution protection, which will equal the Conversion Price; and (ii) the per share dividend, which will be the same percentage of the Conversion Price as applied to determine the per share dividends of the Investors in the Qualified Financing relative to the purchase price paid by the Investors. For the avoidance of doubt, such newly created series of preferred stock described in the preceding sentence shall be pari passu with the Equity Securities issued in the Qualified Financing.

b) If the Company consummates a transaction that is a Deemed Liquidation Event (as defined in the Certificate of Incorporation) while this Note remains outstanding, then the outstanding principal amount of this Note and any unpaid accrued interest shall, immediately prior to the closing of such Deemed Liquidation Event, automatically convert in whole without any further action by the Holder into shares of a newly created series of preferred stock ("**New Senior Preferred Stock**") at a conversion price equal to the Original Issue Price (as defined in the Certificate of Incorporation) for the most senior series of preferred stock of the Company outstanding at such time (the "**New Senior Preferred Conversion Price**"). The New Senior Preferred Stock shall have the identical rights, privileges, preferences and restrictions as the most senior series of preferred stock of the Company outstanding at the time of such conversion, other than with respect to: (i) the per share liquidation preference, which shall be equal to two (2) times in some notes three (3) times in the other notes the New Senior Preferred Conversion Price; (ii) the conversion price for purposes of price-based anti-dilution protection, which will equal the New Senior Preferred Conversion Price; and (iii) the per share dividend, which will be the same percentage of the New Senior Preferred Conversion Price as applied to determine the per share dividends of the holders of the most senior series of preferred stock of the Company outstanding at such time relative to the Original Issue Price for such shares. For the avoidance of doubt, the New Senior Preferred Stock shall be senior to the most senior series of preferred stock of the Company outstanding at such time and shall be pari passu with all other securities into which compulsory convertible notes issued by the Company convert.

c) If this Note has not otherwise been converted pursuant to the above transactions, then, effective as of the Maturity Date, all outstanding principal and accrued and unpaid interest under this Note shall be automatically converted into New Senior Preferred Stock, at a conversion price equal to the New Senior Preferred Conversion Price. No notes have been converted through December 31, 2023.

During 2023, certain Notes that had reached its maturity date were extended by an additional year. In connection with such extension, the conversion rate was amended from 0.80 to 0.75 and liquidation preference is amended from three times to two time in clause (b). All other terms remained the same. The Company accounted for such extension as a modification of the debt instrument.

The fair value amount of the convertible debt and accrued expense is summarized as follows:

	December 31, 2023	December 31, 2022
Current portion		
Conversion rate at 75%	$1,356,796	—
Conversion rate at 80%	$ 606,590	$ 583,510
Total current portion	**1,963,386**	**$ 583,510**
Long Term portion		
Conversion rate at 75%	967,503	2,248,695
Conversion rate at 80%	—	—
Total Long term Portion	**$ 967,503**	**$2,248,695**
Total	**$2,930,889**	**$2,832,205**

Interest expense on the above debt instruments was $164,680 and $124,981 for the years ended December 31, 2023 and 2022, respectively. The Company has elected to record the convertible note at fair value. Changes in the fair value of the Convertible Notes for the years ended December 31, 2023 and 2022 are summarized as follows:

	Year ended	
	December 31, 2023	December 31, 2022
Balance, beginning of the year	$2,832,205	$2,035,848
Addition during the year	150,000	525,000
Interest Accrued	162,742	122,933
Change in fair value	(214,059)	148,424
Total	**$2,930,888**	**$2,832,205**

The fair value of the convertible notes is classified within Level 3 of the fair value hierarchy, using the inputs below to calculate the fair value. The Company used a probability weighted scenario analysis to determine the fair value of the convertible notes. The risk-free rate used in the analysis is based on the yield on a US Government zero-coupon bond, interpolated for the period that corresponds to the time to liquidity as at the valuation date.

	Year ended December 31, 2023	Year ended December 31, 2022
Adjusted Interest rate	4.79% – 5.41%	3.2%
Time to Financing Date	8-10 months	5 months

9. Common stock and Preferred Stock

Authorized Capital

The Company is authorized to issue 20,000,000 shares of common stock, $0.001 par value per share, and 15,000,000 shares of preferred stock, $0.001 par value per share.

Preferred and common stock

At December 31, 2023 and 2022, the Company has issued following preferred stock:

Series	Number of shares issued	Conversion Price	Aggregate Liquidation Preference as of December 31, 2022	Aggregate Liquidation Preference as of December 31, 2023
Series seed	1,078,560	$0.83	$ 1,188,936	$ 1,260,811
Series A	2,592,080	$1.22	4,167,676	4,419,626
Series B	965,200	$2.47	3,148,498	3,338,836
Series B-1	1,480,560	$2.47	4,829,611	5,121,578
Series C	4,432,880	$2.64	15,469,111	16,404,271
Series C-1	530,040	$2.64	1,849,643	1,961,461
Series D	3,680,440	$3.89	18,941,177	20,086,235
Total	**14,759,760**		**$49,594,652**	**$52,592,818**

The significant terms of the common and preferred stock, pursuant to the amended December 2018 articles of incorporation, are as follows:

Preferred stock carries an 8% cumulative preference dividend, payable when declared by the Board of Directors. No dividend has been paid on any series of preferred stock as at December 31, 2023 and 2022. As of December 31, 2023 and 2022, cumulative dividends in arrears for all classes preferred shares was approximately $14,991,827 and $11,992,662, respectively.

Each share of preferred stock shall be convertible at the option of the holder, without the payment of additional consideration, into units of common stock at the conversion price as defined in the shareholders' agreement. The conversion price is subject to adjustment in the event of subsequent issuance of common stock at a lower price than the original conversion price. Each series preferred stock is mandatorily convertible into common stock at the conversion price as defined in the shareholders' agreement on occurrence of an initial public offering ('IPO').

In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, all classes of preferred stockholders would be entitled to receive, in preference to common shareholders, an amount equal to the original issue price plus accrued and unpaid dividends. All series of preferred stock rank pari passu with each other in terms of liquidation preference except series B1 and C1. Part of the amount invested by series B1 and C1 preferred stock as mentioned in the shareholders' agreement rank junior to other preferred stockholders, however, rank pari passu with each other. After the liquidation preference payments to all classes of preferred stockholders have been met, preferred shareholders have unlimited right to participate on a prorated basis with common shareholders.

Holders of the preferred stock shall be entitled to elect 4 members of the Board of Directors and also hold certain protective rights with respect to significant corporate transactions as defined. Each holder of common stock shall be entitled to one vote in respect of each share held.

10. Stock-Based Compensation

On December 14, 2018, the Company authorized an Employee Stock Option Plan 2018 ('ESOP plan') under which 1,719,720 shares of common stock were reserved/authorized by the Company for issuance to directors, consultants and employees of the Company. The ESOP plan entitles director, consultants and employees of the Company to purchase common stock for each option of the Company at a stipulated price, subject to compliance with vesting conditions i.e. employees remaining in employment during the vesting period and director and consultants to continue rendering services during the vesting period. The options of directors and consultants vest as per the schedule prescribed in the grant letter. These can be exercised any time after the vesting period and during their tenure with the Company. However, the exercise period lapses ninety (90) days after the employee, director or consultant leaves the Company.

The Company recognized $Nil and $25,012 of stock-based compensation expense (which is included in research and development expenses) in the Company's Consolidated Statements of Operations and Comprehensive loss for the years ended December 31, 2023 and 2022, respectively.

The fair value of stock-based compensation transactions is measured using the Black-Scholes option pricing model. Measurement inputs include share price on measurement date, exercise price of the instrument, expected volatility (based on weighted average historic volatility for a duration equal to the weighted average life of the instruments, life based on the average of the vesting and contractual periods for employee awards as minimal prior exercises of options in which to establish historical exercise experience), and the risk-free interest rate (based on government bonds). Service and performance conditions attached to the transactions, if any, are not considered in determining fair value. The expected life of the stock options is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the options is indicative of future trends, which may also not necessarily be the actual outcome. The Company is a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical data regarding the volatility of a publicly traded set of peer companies. The expected term of stock options granted to non-employees is between 5 and 7 years. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Stock-based compensation expense attributable to equity awards granted to employees is measured at the grant date based on the fair value of the award. The expense is recognized on a straight-line basis over the requisite service period for awards that vest, which is generally the period from the grant date to the end of the vesting period. Stock-based awards provided to non-employees are measured and expensed as the services are provided and are remeasured at each reporting period until these stock options vest. There were no stock options granted in 2023 and in 2022.

The summary of stock options activity for the years ended December 31, 2023 and 2022 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Time to Expiry
Outstanding as of December 31, 2021	1,384,607	$0.75	8.2 years
Granted during the year	—		
Expired during the year	(283,007)	$1.00	
Exercised during the year	—		
Outstanding as of December 31, 2022	1,101,600	$0.69	7.0 years
Granted during the year	—		
Exercised during the year	—		
Expired during the year	(288,880)	1.07	
Outstanding as of December 31, 2023	812,720	$0.55	6.0 years
Exercisable as of December 31, 2023	812,720	$0.55	6.0 years

The following outlines the outstanding and vested stock options by exercise price at December 31, 2023.

Exercise price	Number of options outstanding	Number of options vested
$0.48	700,720	700,720
$1.00	112,000	112,000
Total	**812,720**	**812,720**

As of December 31, 2023, there is no future compensation cost to be recognized in the Consolidated Statements of Operations and Comprehensive Loss related to stock options granted through December 31, 2023. The intrinsic value of vested and outstanding stock options was approximately $57,000.

11. Income taxes

Both VTI and VTL generated a current taxable loss for the years ended December 31, 2023 and 2022, and therefore the only current income taxes payable were certain minimum taxes.

The effective tax rate for the years ended December 31, 2023 and 2022 differs from the federal statutory income tax rate of 21% principally due to the full valuation allowance recognized against deferred income tax assets, and to a lesser extent due to different tax rates in the jurisdiction of VTL and certain non-deductible expenses for income tax purposes, summarized as follows:

	For the Years Ended December 31,	
	2023	2022
Tax benefit at the federal statutory rate	21%	21%
State tax, net of federal benefit	7%	7%
Permanent differences – principally unrealized gains/losses	8%	-3%
India tax rate differential and other	—%	-3%
Change in valuation allowance	-36%	-22%
Effective income tax rate	0%	0%

Temporary differences and carryforwards that result in deferred tax assets and liabilities were primarily the result of net operating loss carryforwards in the US and India. As at December 31, 2023, VTI has net operating loss carry-forwards of approximately $400,000 in the United States which shall expire through 2035 and $15,300,000 which have no expiration date. As of December 31, 2022, VTL had net operating loss carry-forwards of $8,000,000,expiring in fiscal year ended 2023 through fiscal 2027.

	December 31, 2023	December 31, 2022
VTI – Net Operating Loss Carryforwards	$ 4,390,260	$ 4,243,233
Stock options	139,582	139,582
Accrued compensation	347,199	262,248
Accrued expenses	506,532	507,508
Interest	100,638	55,070
Research and development tax credits	78,388	78,388
VTL – Net Operating Loss Carryforwards	2,626,578	2,569,317
VTL – fixed assets	268,397	346,461
Total deferred tax assets	8,457,574	8,201,806
Less: valuation allowance	(8,457,574)	(8,201,806)
Net deferred tax assets	$ —	$ —

Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carryforwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carryforward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance. As at December 31, 2023, VTI has net operating loss carry-forwards of approximately $15,700,000 in the United States which shall expire as follows: $3.8 million has no expiry, $10.2 million expiry in 2039 and $1.7 million expiry in 2038.

A valuation allowance is established attributable to deferred tax assets recognized on carry forward tax losses by the Company where, based on available evidence, it is more likely than not that they will not be realized. The Company recorded full valuation allowance against its net deferred tax assets on December 31, 2023 and 2022 Significant management judgment is required in determining provision for income taxes,

deferred tax assets and liabilities and any valuation allowance recorded against deferred tax assets. The valuation allowance is based on the Company's estimates of taxable income by jurisdiction in which the Company operates and the period over which deferred tax assets will be recoverable. The change in valuation allowance is approximately $256,000 and $280,000 for the years ended December 31, 2023, and 2022, respectively.

The Company is subject to income taxes and tax audits in many jurisdictions. A certain degree of estimation is thus required in recording the assets and liabilities related to income taxes. Tax audits and examinations can involve complex issues, interpretations, and judgments and the resolution of matters that may span multiple years, particularly if subject to litigation or negotiation.

The Company's investments in its foreign subsidiaries are considered to be permanently invested and no provision for income taxes on the related foreign exchange translation adjustments or income/(loss) of those subsidiaries has been recorded.

The Company does not expect a significant change to the amount of unrecognized tax benefits over the next 12 months. However, any adjustments arising from certain ongoing examinations by tax authorities could alter the timing or amount of taxable income or deductions, of the allocation of income among tax jurisdictions, and these adjustments could differ from the amount accrued. The Corporation's federal and provincial income tax returns filed for all years remain subject to examination by the taxation authorities.

12. Leases

The Company leases offices and laboratory space in India. India under a 5-year lease terminating in December 2023, with a monthly rental payment which ranged from approximately $2,000 to $4,000 per month. From September 2021 through December 2022, the landlord did not charge the Company for contractual rent escalations. The leases were extended for a one-year period ending December 2024 with monthly payments ranging from $2,500 to $2,900 per month. The Company has an intention to renew the leases for the two additional years allowed under the lease agreement.

Operating leases are presented in the Company's consolidated balance sheets as right-of-use assets from leases, current lease liabilities and long-term lease liabilities. The assets and liabilities from our leases are recognized at the lease commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates. Short-term leases, which have an initial term of 12 months or less, are not recorded on the balance sheet. As the Company's operating leases do not provide implicit rates, the Company has utilized its incremental borrowing rate, determined based on the long-term borrowing costs of companies with similar credit profiles, to record its lease obligations. For operating leases, the Company recognizes the minimum rental expense on a straight-line basis based on the fixed components of a lease arrangement. The Company will amortize this expense over the term of the lease beginning with the lease commencement date.

If the Company renews the lease for the entire three-year period, as expected, the annual lease payments will be approximately $30,000 $32,000 and $35,000 in the years ended December 31, 2024, 2025 and 2026, respectively. The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of December 31, 2023:

Lease payments – 2024	$ 30,000
Lease payments – 2025	32,000
Lease payments – 2026	35,697
Total undiscounted operating lease payments – due in 2023	$ 97,694
Less: Imputed interest	(10,634)
Present value of operating lease liabilities	$ 87,060
Current portion of lease liability	$ 25,037
Long-term portion of lease liability	62,023
Total lease liability	$ 87,060
Weighted average remaining lease term in years	3.0

The Right of Use Asset on December 31, 2023 of $87,060 will be amortized over the three year remaining under lease term.

The Right of Use Asset balance on December 31, 2022 was $35,900. Rent expense was approximately $ 36,790 and $ 41,387 for the years ended December 31, 2023, and 2022 respectively. In the U.S., the Company has month to month shared space arrangements.

13. Commitments and contingencies

CRO contract

In December 2018, the Company entered into an agreement with a Contract Research Organization ("CRO") for services to be rendered with respect to the phase 2B clinical trials for the VB-1953 product. Pursuant to such an agreement the Company owed the CRO approximately $2,080,000 as of July 2020. The Company and the CRO entered in an agreement in July 2020 (July Agreement") which called for payments of $400,000 over several installments in 2020 and the remainder upon consummation of a fundraising, as defined in the July Agreement, with any remaining balance to be paid as of March 2021. During 2020, the Company paid $400,000 towards such obligation. As of December 31, 2023 and 2022, the outstanding balance due to the CRO was approximately $1,680,210. Also pursuant to the July Agreement, if the balance remains outstanding as of March 2021, then the balance could convert to Series D preferred stock at the mutually agreed at Series D preferred conversion price as of the July Agreement date. During 2022, the Company and the CRO have agreed by signing a definitive agreement to convert the liability of $1,680,210 into shares of 432,041 shares of Series D preferred shares(based upon the then estimated fair value of such shares), however the shares have not yet been issued. The Company will be required to authorize additional Series D preferred shares in order to consummate this transaction, and accordingly, as of December 31, 2022 and 2023, $1,680,210 was recorded as a liabilities to be settled in equity in the consolidated balance sheet.

Employee Benefits — Gratuity

The Company has a defined benefit gratuity scheme for its employees in India. This gratuity scheme provides for lump sum payment in accordance with the provisions of Payment of Gratuity Act, 1972 to vested employees at retirement or death while in employment or on termination of employment of an amount equivalent to 15 days basic salary payable for each completed year of service or part thereof in excess of six months subject to a limit of INR 1,000,000 (equivalent to approximately $12,000). Vesting occurs upon completion of 5 years of continuous service. A roll forward of the liability balance for the years ended December 31, 2023 and 2022 are as follows:

	December 31, 2023	December 31, 2022
Obligation recognized in balance sheet:		
Beginning of the year	$78,224	$84,542
Benefits paid	(1,504)	(5,138)
Expenses charged to profit or loss	3,323	7,262
Currency translation differences	(183)	(8,442)
End of the year	$79,860	$78,224

Employee Benefits — Leave Encashment

Accumulated Compensated absences or paid leave encashment, which are expected to be encashed within 12 months from the end of the year and are treated as short term employee benefits. The obligation towards the same is measured at the expected cost of accumulating compensated absences as the additional amount expected to be paid as a result of the unused entitlement at the end of the year. Actuarial gains or losses are recognized in the Consolidated statement of Operations and Comprehensive Loss in the year in which they arise. A roll forward of the liability balance for the years ended December 31, 2023 and 2022 are as follows:

	December 31, 2023	December 31, 2022
Obligation recognized in balance sheet:		
Beginning of the year	$83,724	$ 83,724
Benefits paid	(2,074)	(13,863)
Expenses charged to profit or loss	3,263	7,025
Currency translation differences	(266)	6,838
End of the year	$84,647	$ 83,724

Employee Benefits — Provident Fund

In accordance with Indian law, all employees in India are entitled to receive benefits under the 'Provident Fund', which is a defined contribution plan. Both the employee and the employer make monthly contributions to the plan at a predetermined rate (presently at 12%) of the employees' basic salary. These contributions are made to the fund which is administered and managed by the Government of India. The Company's monthly contributions to the above-mentioned plans are charged to consolidated statements of operations loss in the year they are incurred and there are no further obligations under the plan beyond those monthly contributions. The Company's contribution towards the Provident Fund during the years ended December 31, 2023 and 2022 was approximately $1,724 and $2,300, respectively.

Litigation

From time to time, the Company is involved in various disputes, claims, liens and litigation matters arising out of the normal course of business which could result in a material adverse effect on the Company's combined financial position, results of operations or cash flows. Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated. As of December 31, 2023 and 2022, the Company had no outstanding claims or litigation and had no liabilities recorded for loss contingencies.

14. Segments

The Company operates in two segments — the sale of products ("Pharmaceutical Segment") and the development of biotechnology products ("Biotechnology Segment"), with substantially all of the resources of the Company focused on its biotechnology activities. The Company purchases substantially all of the products for the Pharmaceutical Segment from a third-party manufacturer. Other income items relate to corporate financing activities outside of these two segments. Reporting by segment is summarized as follows:

	Year ended December 31, 2023			Year ended December 31, 2022		
Amounts in USD	**Biotechnology**	**Pharmaceutical**	**Total**	**Biotechnology**	**Pharmaceutical**	**Total**
Revenues	$ —	$415,940	$ 415,940	$ —	$382,865	$ 382,865
Gross margin	**—**	**282,532**	**282,532**	**—**	**146,119**	**146,119**
Operating expenses						
Depreciation and amortization	21,193	—	21,193	56,148	—	56,148
SGA & R&D	877,424	151,633	1,029,057	1,099,172	94,981	1,194,153
Total Operating expenses	**898,617**	**151,633**	**1,050,250**	**1,155,321**	**94,981**	**1,250,302**
Other expenses						
Interest expense	164,680		164,680	124,981		124,981
Significant Non cash items	(214,059)		(214,059)	148,424		148,424

Amounts in USD	Year ended December 31, 2023			Year ended December 31, 2022		
	Biotechnology	Pharmaceutical	Total	Biotechnology	Pharmaceutical	Total
Unusual Items	1,581		1,581	(122,290)		(122,290)
Other expenses	**(47,798)**	**—**	**(47,798)**	**151,115**	**—**	**151,115**
Segment income/loss before tax	(850,819)	130,899	(719,920)	(1,306,436)	51,138	(1,255,298)
Income tax	—	—	—	—	—	—
Net income	**(850,819)**	**130,899**	**(719,920)**	**(1,306,436)**	**51,138**	**(1,255,298)**
Net income as per IS before Forex			(719,920)			(1,255,298)

The Company derives revenues from the sale of products, including royalties related to sales of such products and from the license of technology. Substantially all revenues for the years ended December 31, 2023 and 2022 are derived from one customer, a significant pharmaceutical company based in India ("Major Customer"). Revenues for the years ended December 31, 2023 and 2022 are summarized as follows:

	December 31, 2023	December 31, 2022
Sale of Dandruff Lotion and Shampoo Trading	$221,351	$373,995
Licensing and milestone fees	121,100	—
Service fee for arrangements for sale of Dandruff products	67,762	—
Royalty income related to above product sales	5,727	8,870
Total	$415,940	$382,865

In December 2020, the Company entered into a licensing contract for a product to such Major Customer, whereby the Company would be entitled to development and sales-based milestones and royalties on future sales of the product by the Major Customer. In 2021, the Company received $98,490 as a product development milestone payment which was recognized as revenue, as the development process was completed at that time. The Company received a development-based milestones from the Major Customer of $121,100 during the year ended December 31, 2023. No sales-based milestones or royalties have been received under this license through December 31, 2023.

During 2023, the Company amended its arrangement with the Major Customer such that the Company will no longer be responsible for purchasing and selling inventory of the Dandruff Lotion and Shampoo, but instead will receive a net service fee payment for sales of such products made by the Major Customer. These payments are recorded as service fee revenue in the period earned.

15. Due to affiliates

The Company incurred consultancy charges to certain members of the Board of Directors of the Company ("Directors") recognized as selling, general and administrative expenses in the consolidated statements of operations amounting to approximately $100,000 and $100,000 for the years ended December 31, 2023 and 2022, respectively. The amount outstanding to such Directors as at the end of December 31, 2023 and 2022 is approximately $450,000 and $350,000, respectively, which is included in the due to affiliates in the consolidated balance sheet.

The Company incurred compensation expense to the Chief Executive Officer of the Company ("CEO") recognized as selling, general and administrative expenses in the Consolidated Statements of Operations and Comprehensive Loss amounting to approximately $260,000 for the each of the years ended December 31, 2023 and 2022. The amount outstanding as at the end of December 31, 2023 and 2022 to the CEO is $692,495 and $ 508,789, respectively, which is included in Salary and Employment benefits Payable in the Consolidated Balance Sheets.

Certain Directors have provided short term advances to the Company from time to time, amounting to $2,500 as of December 31, 2023. This is included in due to affiliates in the accompanying Consolidated Balance Sheets and was yet to repaid in full in 2024.

16. Other Income

The Company has earned approximately $103,400 in the Service Export Incentive in India from Indian government authorities during the year ended December 31, 2022. This is earned by the Indian subsidiary VTL because of export of services to VTI under the rules and regulations of the export promotion incentives announced by the Indian government from time to time. No such amounts were earned in 2023.

17. Subsequent events

For the consolidated financial statements as at and for the year ended December 31, 2023, we have evaluated subsequent events through the date the consolidated financial statements were available to be issued and determined that there have been no events that have occurred that would require adjustments to our disclosures in the consolidated financial statements except for the transaction described below:

During 2024, the Company has received the written subscription agreement of $320,000 through the issuance of convertible notes under the same terms as described above.

Vyome Therapeutics Inc. and Subsidiary
Consolidated financial statements (unaudited)
Nine months ended September 30, 2024, and September 30, 2023

Vyome Therapeutics, Inc. and Subsidiary

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VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS AS OF (UNAUDITED)

(Amount in USD)	September 30 2024	December 31 2023
Assets		
Current assets		
Cash and cash equivalents	$ 48,872	$ 16,647
Accounts receivables, net	348	66,816
Other current assets	86,249	86,362
Total current assets	**135,469**	**169,825**
Non-current assets		
Property and equipment, net	73,930	85,931
Intangible asset – shell company	314,191	314,191
Goods and service tax and other credits receivable	696,728	697,827
Deferred offering costs	66,415	66,415
Right-of-use of asset, net	67,583	87,060
Total non-current assets	**1,218,847**	**1,251,424**
Total assets	**$ 1,354,316**	**$ 1,421,250**
Liabilities and stockholders' deficit		
Current liabilities		
Accounts payable and accrued expenses	$ 847,414	$ 910,536
Liabilities to be settled in equity	—	1,680,210
Due to Affiliates	97,831	452,432
Operating Lease Liability – current portion	27,498	25,037
Salary and post-employment benefits payable	886,066	1,375,706
Other Current liability	76,622	69,589
Convertible debt – Current portion	2,304,850	1,963,386
Total current liabilities	**4,240,281**	**6,476,895**
Non-current liabilities		
Convertible debt – net of current portion	1,183,131	967,503
Operating lease liability – net of current portion	40,904	62,023
Total non-current liabilities	**1,224,035**	**1,029,526**
Total liabilities	**$ 5,464,316**	**7,506,422**
Commitments and contingencies		
Stockholders' deficit		
Common stock, 20,000,000 shares authorized, 1,893,120 shares issued and outstanding at December 31, 2023 and 2022	1,892	1,892
Preferred stock, 16,000,000 shares authorized, 15,303,417 and 14,759,760 shares issued and outstanding as of September 30, 2024 and December 31, 2023	47,419,384	46,984,875
Additional paid in capital	3,438,719	643,709
Accumulated deficit	(55,205,511)	(53,950,682)
Accumulated other comprehensive income	235,516	235,034
Total stockholders' deficit	**(4,110,000)**	**(6,085,172)**
Total liabilities and stockholders' deficit	**$ 1,354,316**	**$ 1,421,250**

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

(Amount in USD)	January 01, 2024, to September 30, 2024	January 01, 2023, to September 30, 2023
Revenue		
Revenue	$ 195,516	$ 346,571
Cost of goods sold	(63,307)	(133,241)
Gross profit	**$ 132,209**	**$ 213,330**
Operating expenses		
Depreciation and amortization	13,483	16,425
Selling, general and administrative	727,336	606,594
Research and development expenses	255,645	251,498
Total operating expenses	**$ 996,464**	**$ 874,517**
Operating loss	(864,255)	(661,187)
Other income/(expense), net:		
Interest expenses	$ (153,229)	$ (121,409)
Other income(loss), net	2,341	(1,759)
Fair value adjustment	(239,686)	327,773
Total other income, net	**(390,574)**	**204,605**
Net loss	**$(1,254,829)**	**$ (456,582)**
Other comprehensive income, net of tax		
Foreign currency translation adjustments	(35)	4,089
Other comprehensive income / (loss), net of tax	**$ (35)**	**$ 4,089**
Total comprehensive loss	**$(1,254,864)**	**$ (452,493)**
Net Loss per share:		
Loss per share – basic and diluted	**$ (0.66)**	**$ (0.24)**
Weighted average number of shares – basic and diluted	1,893,120	1,893,120

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIT (UNAUDITED)

For the nine months ended September 30, 2024 and September 30, 2023

(Amount in USD)	Common stock		Preferred stock		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income (Loss)	Total Stockholders Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	1,893,120	$1,892	14,759,760	$46,984,875	$ 643,709	$(53,207,977)	$212,413	$(5,365,089)
Stock based expense								—
Net loss for the period						(456,582)		(456,582)
Foreign currency translation							4,735	4,375
Balance at September 30, 2023	**1,893,120**	**$1,892**	**14,759,760**	**$46,984,875**	**$ 643,709**	**$(53,664,559)**	**$216,787**	**$(5,817,296)**
Balance at December 31, 2023	1,893,120	$1,892	14,759,760	$46,984,875	$ 643,709	$(53,950,682)	$235,034	$(6,085,172)
Stock-based compensation								
Net loss						$ (1,254,828)		(1,254,828)
Issuance of shares in settlement of liability			432,041	$ 432	$1,679,778			1,680,210
Issuance of shares in settlement of accrued compensation liability			—	$ —	$1,115,232			1,115,232
Conversion of Note to Preferred shares			111,616	$ 434,077	$ —			434,077
Foreign currency translation adjustment							482	482
Balance at September 30, 2024	**1,893,120**	**$1,892**	**15,303,417**	**$47,419,384**	**$3,438,719**	**$(55,205,510)**	**$235,516**	**$(4,110,000)**

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(Amount in USD)	January 01, 2024, to September 30, 2024	January 01, 2023, to September 30, 2023
Cash flows from operating activities		
Net loss	**$(1,254,829)**	**$(456,582)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13,483	16,424
Stock-based compensation	—	—
Liabilities to be settled in equity	—	—
(Gain) loss on fair value adjustment of convertible debt	239,686	(327,773)
Non cash accrued Interest expense	$ 137,942	$ 119,751
Changes in assets and liabilities:		
Accounts receivables, net	66,468	(80,422)
Inventories, net	—	—
Prepaid expenses and other current assets	113	40,587
Other assets	20,576	38,976
Accounts payable & accrued expenses	(63,122)	35,970
Due to Affiliates	64,457	75,000
Post employment benefits	175,593	173,738
Deferred income		
Other Liabilities	(11,625)	44,339
Net cash used in operating activities	**$ (611,258)**	**$(489,644)**
Cash flows from investing activities:		
Proceeds from sale of fixed assets/(Purchase of fixed assets)	(1,482)	—
Net cash used in investing activities	**(1,482)**	**—**
Cash flows from financing activities:		
Proceeds from convertible debt	613,542	150,000
Advance from Affiliates	30,942	(30,151)
Net cash from financing activities	**$ 644,484**	**$ 119,849**
Effect of exchange rate changes on cash and cash equivalents	479	4,372
Net (Decrease)/Increase in cash and cash equivalents	32,223	(365,423)
Cash and cash equivalents at beginning of the year	16,647	458,245
Cash and cash equivalents at end of the year	**$ 48,870**	**$ 92,822**
Supplemental non-cash and financing activities:		
Shares issued in settlement of liability to vendor to Additional paid in capital	$ 1,680,210	$ —
Exchange of accrued fees to director for stock options to Additional paid in capital	450,000	—
Exchange of accrued compensation for stock options to Additional paid in capital	$ 665,232	$ —

The accompanying notes are an integral part of these consolidated financial statements.

VYOME THERAPEUTICS INC. AND SUBSIDIARY

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts are in US Dollars except per share data and as stated otherwise)

1. Organization and principal activities

Business:

Vyome Therapeutics, Inc. ("VTI"), a Delaware corporation, was incorporated on August 22, 2017. VTI was formed with the intent of operating the R&D business of Vyome Biosciences India Private Limited, India (the "R&D Business"), which was transferred to Vyome Therapeutics Limited (a wholly owned subsidiary of VTI) pursuant to a Demerged order of National Company law Tribunal ("NCLT") in India, formally consummated in December 2018. VTI and the wholly owned subsidiary in India, Vyome Therapeutics Limited ("VTL") are collectively referred to as the "Company" or "Vyome". "R&D business" is defined as novel drug development in the area of immune-inflammatory diseases space and the commercial exploitation of the same.

The Company is a Princeton, NJ-based clinical stage specialty pharmaceutical company working to treat immune-inflammatory and rare diseases of unmet need with next generation therapeutic solutions. The lead program VT-1953, a topical gel with a novel molecule to treat signs and symptoms of Malignant Fungating wounds, a potential orphan drug program. The Company is planning to have discussions with Food & Drug Administration (FDA) on the pivotal trial protocol in the first quarter of 2025. The Company also has Pre-Investigative New Drug application stage ophthalmic drops program, a potentially orphan drug program, and a repurposed immune modulator to treat steroid-sparing anterior uveitis. Another late clinical stage program, VB 1953, for moderate to severe acne has successfully completed its Phase II clinical trial and this program is Phase 3 ready. The Company may experience delays in the conduct of clinical trials of its candidates. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Any delays in completing the Company's clinical trials will increase its costs, slow down its product development, timeliness, and approval process, and delay its ability to generate revenue.

The Company also is developing other assets for treating immune-inflammatory diseases which are in pre-clinical or early clinical development.

The Company also has commercialized novel reformulated topical anti-fungal products in India after two such products successfully completing clinical testing in India. The Company has entered into licensing and a marketing agreement with Sun Pharma group of companies to sell a family of novel topical anti-fungal products owned by the Company in India. The Company uses third party entities to manufacture the products.

Since its inception, the Company has devoted substantially all its efforts to drug development, business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of pre-clinical studies, clinical studies and clinical trials, the need to obtain marketing approval for its drug candidates and its consumer products, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to transition from pilot scale manufacturing to large scale production.

The Company has signed a definitive agreement to do a reverse merger into a Nasdaq listed company.

2. Summary of Significant Accounting Policies

a) Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and pursuant to the accounting and disclosure rules and regulations of the Securities and Exchange Commission ("SEC"), and reflect all adjustments consisting only of normal recurring adjustments of the Company, which are, in the opinion of management, necessary for a fair presentation of the financial position as of September 30, 2024 and December 31, 2023, and the results of operations, and cash flows for the periods presented. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

The Company organized its operations into two operating segments. The segments reflect the way the Company evaluates its business performance and manages its operations by the Company's chief operating decision maker ("CODM") for making decisions, allocating resources and assessing performance. The Company's CODM has been identified as the chief executive officer. The Company determined it has in two operating segments: (1) Sale of Products and (2) biotechnology segment. The Company's reportable segments are strategic business units that offer different products and services. They are managed separately because each business requires different technology and marketing strategies.

As the Company's long-lived assets, except for the intangible asset and deferred offering costs are substantially all located in India, and all of the Company's revenue and expense related to the sale of products are derived from within India, no geographical segments are presented.

The Company operates in two segments- Sale of products and biotechnology activities- see Note 14.

b) Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, VTL. All intercompany accounts and transactions have been eliminated in the consolidation.

c) Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. For the nine months ended September 30, 2024, and 2023, the Company has generated a net loss of $ 1,254,829 and $ 456,582 respectively. As of September 30, 2024, the Company's current liabilities exceed its current assets by approximately $ 4.1 million. ✓ The Company's major sources of funds to date have been through the sale of preferred stock and the issuance of convertible debt. The Company does not believe it has sufficient funds to finance the operating requirements for at least the next 12 months from the issuance date of these consolidated financial statements. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Obtaining additional financing to support the successful development of the Company's contemplated plan of drug development and operations and its transition, ultimately, to the attainment of profitable operations are necessary for the Company to continue operations. The Company may raise additional funding from its current set of investors. In addition, a financial advisor has been engaged to pursue additional capital funding or other strategic transactions and the Company will continue to seek funds through debt or equity financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or other sources of financing. However, there can be no assurances that such financing or other strategic transactions will be available on acceptable terms, or at all. If the Company is unable to raise additional funds, it will need to do one or more of the following:

- Delay clinical trials and processes;
- License third parties to develop and commercialize products or technologies that it would otherwise seek to develop and commercialize itself;
- Seek strategic alliances or business combinations;
- Attempt to sell the Company;
- Cease operations; or
- Declare bankruptcy

The Company continues to raise additional capital through the issuance of convertible notes. The Company is in discussions with investment bankers to raise additional capital in the public or private markets. There is no assurance that such financing can be completed. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is implementing plans to reduce expenses and seek additional financing. However, there can be no assurance that these plans will be successful. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The consolidated financial statements do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

d) Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results, as determined at a later date, could differ from those estimates. Significant estimates used in preparing these audited consolidated financial statements include the realization of deferred tax assets, timing of the recognition of research and development costs, fair value of debt and equity-based instruments, and future obligations under employee benefit plans.

e) Foreign Currency Translation and Transactions

The Company also operates in India, which may give rise to significant foreign currency risks from fluctuations and the degree of volatility of foreign exchange rates between the US dollar and the Indian Rupee.

The Company's functional currency is the United States Dollar. The functional currency of its Indian subsidiary is Indian National Rupees. Consequently, revenues and expenses of operations of the Indian subsidiary are translated into United States Dollars using average period exchange rates, while assets and liabilities of the Indian subsidiary are translated into United States Dollars using the year-end exchange rate in effect at the balance sheet dates. Adjustments resulting from the translation of functional currency financial statements to reporting currency are accumulated and reported as a part of Accumulated Other Comprehensive Income, a separate component of stockholders' equity in the accompanying consolidated balance sheets.

Transactions in foreign currencies are translated at the exchange rate prevailing on the date of the transaction. Resulting gains or losses from the settlement of such foreign currency transactions are included in the consolidated statements of operations. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates in effect on the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are expressed in functional currency at the historical exchange rates. Losses resulting from foreign currency transactions amounting to $(35) and $4,089 for the nine months ended September 30, 2024, and 2023 respectively are included in the consolidated statements of operations under the caption selling, general and administrative expenses.

f) Cash and Cash Equivalents

Cash includes all highly liquid instruments with a maturity of three months or less when purchased. The Company maintains its cash balances in financial institutions which are insured by the Federal Deposit Insurance Corporation ("FDIC"). At various times during the year, such balances may exceed the FDIC limit. The Company has not experienced any credit losses associated with its balances in such accounts. Cash held in the U.S. bank account as of September 30, 2024, and December 31, 2023, was approximately $ 25,675 and $ 5,521, respectively. Cash held in India as of September 30, 2024, and December 31, 2023, was approximately $23,197 and $11,126, respectively.

g) Accounts Receivable, net

Accounts receivable is generally recorded at the invoiced amounts, net of an allowance for expected losses. The Company establishes credit terms for new customers based upon management's review of their credit information and project terms and performs ongoing credit evaluations of its customers, adjusting credit terms when management believes appropriate based upon payment history and an assessment of the customer's current credit worthiness. We record an allowance for credit losses for estimated losses resulting from the failure of our customers to make the required payments. Judgments are made with respect to the collectability of accounts receivable based on historical experience, current payment practices, and current economic trends based on our expectations over the expected life of the receivables, generally ninety days or less. Actual credit losses could differ from those estimates. Management determined that no allowance for doubtful accounts was necessary as of September 30, 2024, and December 31, 2023.

h) Property and equipment, net

Property and equipment, the net is stated as net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, summarized as follows:

Computers and software	3 years
Office equipment	5 years
Furniture and Fixtures	10 years
Lab machinery	10 years
Leasehold improvements	Lower of estimated useful life or remaining period of lease term

Repairs and maintenance costs are expensed as incurred; major renewals and betterments are capitalized. When assets are disposed of, the assets and related allowances for depreciation and amortization are eliminated from the accounts, and any resulting gain or loss is reflected in operations.

i) Goods and Service Tax and Other Credits Receivable

The Company has indirect tax credit carryforwards arising in India, which may be utilized or refunded as VTL generates sales to third parties or invoices to VTI pursuant to intercompany transfer pricing arrangements. The Company expects to utilize these indirect tax credit carryforwards over a 4-to-5-year period.

j) Intangible Assets

On August 21, 2021, Vyome acquired the majority of the outstanding shares (purchase of substantially all of the outstanding shares of preferred stock) of Livechain, Inc., ("LICH") for $220,000. The total costs of the asset acquisition were $314,191. LICH is an inactive non-reporting shell ("Shell Company") that trades on the bulletin board under the ticker symbol LICH. As of the date of the transaction and through September 30, 2024, LICH had no operations. LICH did not meet the definition of a business and therefore was accounted for as an asset acquisition of the shell company, a single indefinite-lived asset.

Intangible assets with indefinite lives (i.e., non-reporting shell) are not amortized; rather, they are tested for impairment annually or whenever events or circumstances exist that would make it more likely than not that an impairment exists.

k) Impairment of Long-Lived Assets

The Company evaluates all long-lived assets for impairment annually, or sooner if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If the carrying amount is not fully recoverable, an impairment loss is recognized to reduce the carrying amount to fair value and is charged to expense in the period of impairment. As of September 30, 2024, and December 31, 2023, management has determined that these assets are not impaired.

l) Revenue Recognition

The Company recognizes revenue under ASC Topic 606, "*Revenue from Contracts with Customers*" ("ASC 606"). The Company determines revenue recognition through the following steps:

- Step 1: Identify the contract with the customer;
- Step 2: Identify the performance obligations in the contract;
- Step 3: Determine the transaction price;
- Step 4: Allocate the transaction price to the performance obligations in the contract; and
- Step 5: Recognize revenue when the company satisfies a performance obligation.

The Company records sales of its dermatological products to the pharmaceutical company when performance obligations with customers are satisfied. The Company's performance obligation is a promise to transfer a distinct good to the customer and each distinct good represents a single performance obligation. Such performance obligations are satisfied at a point in time and revenues are recognized when all rights and rewards of ownership are transferred. The majority of the Company's products are shipped by common carriers resulting in recognition of revenues upon shipment at which time control passes to the customer. Revenue is measured at the amount of consideration the Company expects to receive in exchange for the transferring of products. Customers may be entitled to cash discounts, typically denoted at the time of invoicing and shipping. Such amounts are considered to be variable consideration under ASC 606. An estimate for cash discounts is included in the transaction price as a component of sales and is estimated based on the satisfaction of outstanding receivables and historical performance. The Company does not have any material financing terms as payment is received shortly after the transfer of control of the products to the customer within a period of 30-60 days.

Pursuant to licensing and marketing contracts, the Company receives payments from its pharmaceutical company marketing partner for the right to distribute the products ("royalties"). Such royalty payments are linked to the net sales value of the products by its marketing partner to third parties and are recognized in the period to which the royalty relates. Such amounts are recorded under Revenue from operations in the Consolidated Statements of Operation and Comprehensive Loss.

The Company recognizes milestone payments under the license and marketing agreements when all performance obligations related to the identified performance obligations are completed.

m) Cost of products sold

The cost of products sold represents the cost of manufacturing the products supplied by third-party manufacturers.

n) Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include employee compensation and overheads. External expenses include development, clinical trials, statistical analysis and report writing, and regulatory compliance costs incurred with clinical research organizations and other third-party

vendors. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates have been made as a result of the service provided, the Company may record net prepaid or accrued expenses relating to these costs. Payments made to third parties that perform research and development services on the Company's behalf are expensed as services are rendered, or as contractually agreed.

o) Stock-based Compensation

The Company accounts for stock options granted to employees and non-employees at fair value, which is measured using the Black-Scholes Option pricing model. The fair value measurement date for employee awards is the date of the grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grant, generally equal to the vesting period and uses the straight-line method to recognize stock-based compensation.

The Company's policy is to account for forfeitures of awards when they occur in accordance with ASC 718, *Compensation-Stock Compensation*. The Company reverses compensation cost previously recognized, in the period the award is forfeited, for an award that is forfeited before completion of the requisite service period.

The Company utilizes the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value options granted. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying stock issuable upon exercise of the options, expected life of the options, risk-free interest rate, expected dividend yield, and expected volatility from peer public companies of the price of the underlying stock.

As the Company's common stock has not been publicly traded, its board of directors periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its common stock prepared by an independent valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The expected life of the stock options in years is estimated using the "simplified method," as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, as the Company has no historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected life of the option. The expected dividend yield is zero as the Company has no history of paying dividends and no plans to do so in the near term.

p) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards in the consolidated financial statement. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in unaudited consolidated statements of operations in the period that includes the enactment date.

Valuation allowances are recognized to reduce deferred tax assets to the amount that will more likely than not be realized. In assessing the need for a valuation allowance, management considers all available evidence for each jurisdiction including past operating results, estimates of future taxable income and the feasibility of ongoing tax planning strategies. When the Company changes its

determination as to the amount of deferred tax assets that can be realized, the valuation allowance is adjusted with a corresponding impact to income tax expense in the period in which such determination is made.

The Company also accounts for uncertain tax positions in accordance with ASC Topic 740, *Income Taxes*. This guidance prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. As of September 30, 2024, and December 31, 2023, the Company had no uncertain tax positions that affected its financial position and its results of operations or its cash flows and will continue to evaluate for uncertain tax positions in the future. There are no interest costs or penalties provided for in the Company's consolidated financial statements for the nine months ended September 30, 2024, and 2023. If at any time the Company should record interest and penalties in connection with income taxes, the interest, and the penalties will be expensed within the general and administrative expenses category in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

q) Leases

The Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 842, "Leases", establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. Lessor accounting under the new standard is substantially unchanged. Additional qualitative and quantitative disclosures are also required.

The Company adopted the following practical expedients and accounting policies elections related to this standard:

- Short-term lease accounting policy election allowing lessees to not recognize ROU assets and liabilities for leases with a term of 12 months or less; option to not separate lease and non-lease components in the Company's lease contracts; and
- The package of practical expedients applied to all of its leases, including (i) not reassessing whether any expired or existing contracts are or contain leases, (ii) not reassessing the lease classification for any expired or existing leases, and (iii) not reassessing the capitalization of initial direct costs for any existing leases.

Disclosures related to the amount, timing and uncertainty of cash flows arising from leases are included in Note 12.

r) Notes Payable

The Company has elected to account for notes payable to a shareholder using the fair value option in accordance with the guidance contained in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 825-10-25. The fair value option provides an option to elect fair value as an alternative measurement for selected financial assets, financial liabilities, unrecognized firm commitments, and written loan commitments. See Note 8 for additional information. The Company adopted ASU 2020-06 effective December 31, 2021. ASC 815-40-65-1(d) also allows a reporting entity to make a one-time irrevocable election to apply the fair value option in ASC 825-10 as of the date of adoption for any liability classified convertible securities that are within the scope of ASC 825-10. The impact of electing the fair value option would be reflected through a cumulative effect adjustment to the opening retained earnings balance as of the beginning of the first reporting period a reporting entity adopted ASU 2020-06. However, since the Company had previously adopted the fair value option for its convertible debt, there was no impact on the adoption of ASU 2020-06.

s) Fair Value Measurements

The Company considers its cash and cash equivalents, accounts receivable, and accounts payable to meet the definition of financial instruments, and the carrying amounts of such instruments

approximated their fair values due to the short maturities of these instruments. The Company records the convertible debt at fair value.

The Company measures fair value as required by the ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, there exists a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2 — Inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

Level 3 — Unobservable inputs for the asset or liability are only used when there is little if any, market activity for the asset or liability at the measurement date.

The Company utilizes a Probability Weighted Expected Return Model ("PWERM") to value the convertible debt. The quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's convertible debt that is categorized within Level 3 of the fair value hierarchy included the discount rate and expected financing date. The other factors used in the calculation of fair value are contractual terms of the convertible note instruments.

The following table sets forth the financial assets, measured at fair value, by level within the fair value hierarchy as of September 30, 2024, and December 31, 2023

	September 30, 2024	December 31, 2023
Level 3		
Convertible debt	$3,487,981	$2,930,889

t) Basic and diluted net loss per common share

Net loss per share information is determined using the two-class method, which includes the weighted average number of shares of common stock outstanding during the period and other securities that participate in dividends (a "participating security"). The Company considered its Preferred Stock to be participating securities because the shares included rights to participate in dividends with the common stock.

Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. The net loss attributable to common stockholders is calculated by adjusting the net loss of the Company for the accretion on the Preferred Stock. Net losses are not allocated to preferred stockholders as they do not have an obligation to share in the Company's net losses. In periods with net income attributable to common stockholders, the Company would allocate net income first to preferred stockholders based on dividend rights under the Company's certificate of incorporation and then to preferred and common stockholders based on ownership interests. Diluted net loss per share attributable to common stockholders is computed using the more dilutive of (1) the two-class method or (2) the if-converted method.

During the nine months ended September 30, 2024, and 2023, diluted earnings per common share is the same as basic earnings per common share because, as the Company incurred a net loss during

each period presented, the potentially dilutive securities from the assumed exercise of all outstanding stock options would have an anti-dilutive effect. The dilutive shares as of September 30, 2023, not included in the loss per share calculation, include 14,759,760 shares of common stock issuable upon conversion of preferred stock and 1,101,600 shares potentially issuable under stock options. The dilutive shares as of September 30, 2024, not included in the loss per share calculation, include 15,303,417 shares of common stock issuable upon conversion of preferred stock and 1,455,750 shares potentially issuable under stock options.

u) Post Employment benefits

The Subsidiary in India has a defined benefit gratuity scheme for its employees in India. This gratuity scheme provides for lump sum payment in accordance with the provisions of the Payment of Gratuity Act, 1972 to vested employees at retirement or death while in employment or on termination of employment of an amount equivalent to 15 days basic salary payable for each completed year of service or part thereof in excess of nine months subject to a limit of INR 2,000,000 (equivalent to approximately $ 24,000). Vesting occurs upon completion of 5 years of continuous service.

Accumulated Compensated absences, which are expected to be encashed within 12 months from end of the year, are treated as short-term employee benefits. The obligation towards the same is measured at the expected cost of accumulating compensated absences as the additional amount expected to be paid as a result of the unused entitlement at the end of the year. Actuarial gains or losses are recognized in the Consolidated Statement of Operations and Comprehensive Loss in the year in which they arise.

v) Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB and are early adopted by the Company or adopted as of the specified effective date. There were no recent accounting pronouncements that impacted the Company or are expected to have a significant effect on its consolidated financial statements.

3. Other current assets

Other current assets consist of the following:

Advances to suppliers	$ 7,011	$18,764
Others	79,238	67,598
Total	**$86,249**	**$86,362**

4. Property and equipment, net

Property and equipment, net consist of the following:

	September 30, 2024	December 31, 2023
Buildings and Improvement	$ 160,458	$ 160,458
Computer and office equipment	85,449	85,449
Furniture & fixtures	14,953	13,471
Laboratory equipment	488,753	488,753
Total	749,613	748,131
Accumulated depreciation	(675,683)	(662,199)
Net fixed assets	**$ 73,930**	**$ 85,932**

Depreciation expense is included in selling, general, and administrative expenses in the accompanying Consolidated Statements of Operations and Comprehensive Loss and was $13,483 and $16,425 for the nine months ended September 30, 2024, and September 30, 2023, respectively.

5. Goods and service tax and other credits receivable

The Company's balance of goods and service tax and other credits receivable from government authorities as of September 30, 2024, and December 31, 2023, consist of the following:

	September 30, 2024	December 31, 2023
Tax deducted at source and tax collected at source receivable	$ 29,825	$ 14,158
Goods and service tax refund receivable	—	4,736
Input goods and service tax credit	666,904	678,933
	$696,728	$697,827

6. Accounts payable and Accrued expenses

Accounts payable and accrued expenses as of September 30, 2024, and December 31, 2023 consist of the following:

	September 30, 2024	December 31, 2023
Accounts payable	$501,606	$589,839
Accrued expenses	345,808	320,698
	$847,414	**$910,537**

7. Salary and post-employment benefits payable

Salary and post-employment benefits payable as of September 30, 2024, and December 31, 2023, consist of the following:

	September 30, 2024	December 31, 2023
Salaries payable	$ 740,337	$1,211,205
Accrued leave encashment (note 12)	78,262	84,647
Accrued gratuity plan (note 12)	67,465	79,854
	$8,886,066	**$1,375,706**

In June 2024, an officer and a director of the Company agreed to forgo accrued salaries, and consulting fees payable of $1,115,232 in exchange for the issuance of stock options for the purchase of 643,030 shares of common stock (see Note 10). The Company accounted for this debt extinguishment as a capital contribution since the liability was with related parties. Accordingly, the difference between the liability extinguished of $1,115,232 and the fair value of the stock options issued ($379,950) of $ 735,282 is considered a capital contribution.

8. Convertible debt

Commencing in October 2020, the Company began raising money under a compulsorily convertible promissory note (the "Promissory Notes") pursuant to a Subscription Agreement (the "Subscription Agreement"). The Promissory Note was issued as part of a private placement (the "Offering") for the sale of up to $2,395,542 (which was subsequently expanded) of secured convertible promissory notes (collectively, the "Promissory Notes") for a period until three years of maturity. The Promissory Notes bear interest at a rate of eight percent (8%) per annum, on a non-compounding basis, and are due and payable on the earlier of (i) the date upon which the Promissory Notes are converted into equity securities of the Company, or (ii) at maturity in three (3) years ("Maturity Date"). Significant conversion terms of the Promissory Notes are as follows:

a) In the event that the Company issues and sells shares of its equity securities ("**Equity Securities**") to investors (the "**Investors**") prior to the Maturity Date in an equity financing with total

proceeds to the Company of not less than $10,000,000 (excluding the conversion of the Promissory Notes or other convertible securities issued for capital raising purposes (*e.g.*, Simple Agreements for Future Equity) (a "**Qualified Financing**"), then the outstanding principal amount of this Note and any unpaid accrued interest shall automatically convert in whole without any further action by the Holder into Equity Securities sold in the Qualified Financing at a conversion price equal to the cash price per share paid for Equity Securities by the Investors in the Qualified Financing multiplied by 0.75 in some notes or 0.8 in some other notes; provided, that if such Qualified Financing is also a Deemed Liquidation Event (as defined in the Company's Certificate of Incorporation, as amended, restated, and otherwise in effect from time to time, the "**Certificate of Incorporation**"), shall govern with respect to the conversion of this Note. The issuance of Equity Securities pursuant to the conversion of this Note shall be upon and subject to the same terms and conditions applicable to Equity Securities sold in the Qualified Financing. Notwithstanding this paragraph, if the conversion price of the Notes as determined pursuant to this paragraph (the "**Conversion Price**") is less than the price per share at which Equity Securities are issued in the Qualified Financing, the Company may, solely at its option, elect to convert this note into shares of a newly created series of preferred stock having the identical rights, privileges, preferences and restrictions as Equity Securities issued in the Qualified Financing, and otherwise on the same terms and conditions, other than with respect to (if applicable): (i) the per share liquidation preference and the conversion price for purposes of price-based anti-dilution protection, which will equal the Conversion Price; and (ii) the per share dividend, which will be the same percentage of the Conversion Price as applied to determine the per share dividends of the Investors in the Qualified Financing relative to the purchase price paid by the Investors. For the avoidance of doubt, such newly created series of preferred stock described in the preceding sentence shall be pari passu with the Equity Securities issued in the Qualified Financing.

b) If the Company consummates a transaction that is a Deemed Liquidation Event (as defined in the Certificate of Incorporation) while this Note remains outstanding, then the outstanding principal amount of this Note and any unpaid accrued interest shall, immediately prior to the closing of such Deemed Liquidation Event, automatically convert in whole without any further action by the Holder into shares of a newly created series of preferred stock ("**New Senior Preferred Stock**") at a conversion price equal to the Original Issue Price (as defined in the Certificate of Incorporation) for the most senior series of preferred stock of the Company outstanding at such time (the "**New Senior Preferred Conversion Price**"). The New Senior Preferred Stock shall have the identical rights, privileges, preferences and restrictions as the most senior series of preferred stock of the Company outstanding at the time of such conversion, other than with respect to: (i) the per share liquidation preference, which shall be equal to two (2) times in some notes three (3) times in the other notes the New Senior Preferred Conversion Price; (ii) the conversion price for purposes of price-based anti-dilution protection, which will equal the New Senior Preferred Conversion Price; and (iii) the per share dividend, which will be the same percentage of the New Senior Preferred Conversion Price as applied to determine the per share dividends of the holders of the most senior series of preferred stock of the Company outstanding at such time relative to the Original Issue Price for such shares. For the avoidance of doubt, the New Senior Preferred Stock shall be senior to the most senior series of preferred stock of the Company outstanding at such time and shall be pari passu with all other securities into which compulsory convertible notes issued by the Company convert.

c) If this Note has not otherwise been converted pursuant to the above transactions, then, effective as of the Maturity Date, all outstanding principal and accrued and unpaid interest under this Note shall be automatically converted into New Senior Preferred Stock, at a conversion price equal to the New Senior Preferred Conversion Price.

In August 2024, two Convertible Notes with an aggregate principal plus accrued interest of $ 434,077 were converted in 111,616 shares of Series D preferred stock at $3.889 per share. No other Convertible Notes have been converted through September 30, 2024.

During 2023 and 2024, certain Notes that had reached their maturity date were extended by an additional year. In connection with such extension, the conversion rate was amended from 0.80 to 0.75 and liquidation preference was amended from three times to two times in clause (b). All other terms remained the same. The Company accounted for such extension as a modification of the debt instrument. In the period

of April to September 2024, seven Notes have matured out of which two noteholders converted to Series D Preferred stock at maturity as per the terms of the Notes. The Company and other Noteholders are discussing extending the term with the board and shareholders' approval.

In July 2024, the Company began offering investors the opportunity to participate in a Securities Purchase Agreement providing investors the right to certain equity instruments and other equity rights, some of which are dependent upon the completion of the Merger. An aggregate of 18 investors agreed to participate in such financing through September 30, 2024, for an aggregate of approximately $7.3M, of which $ 413,542 was received through September 30, 2024, in the form of bridge notes. The bridge notes have similar terms to the above convertible notes except that there is a one-year maturity. The remainder large part committed funds will be placed in an escrow account six to seven days before the Merger, pending completion of the Merger, however, these funds have not been received as of September 30, 2024.

The fair value amount of the convertible debt and accrued expense is summarized as follows:

	September 30, 2024	December 31, 2023
Current portion		
Conversion rate at 75%	$1,758,973	$1,356,796
Conversion rate at 80%	$ 545,877	$ 606,590
Total current portion	**2,304,850**	**$1,963,386**
Long Term portion		
Conversion rate at 75%	1,183,131	967,503
Conversion rate at 80%	—	—
Total Long term Portion	**$1,183,131**	**967,503**
Total	**$3,487,981**	**$2,930,889**

Interest expense on the above debt instruments was $137,942 and $119,751 for the nine months ended September 30, 2024, and 2023, respectively. The Company has elected to record the convertible note at fair value. Changes in the fair value of the Convertible Notes for the nine months ended September 30, 2024, and 2023 are summarized as follows:

	Nine months ended September 30, 2024	Nine months ended September 30, 2023
Balance, beginning of the period	$2,930,888	$2,832,205
Additional notes issued	613,542	150,000
Notes repaid		
Notes and accrued interest converted to preferred stock	(434,077)	—
Interest Accrued	137,942	119,751
Change in fair value	239,686	(327,773)
Total	**$3,487,981**	**$2,774,184**

The fair value of the convertible notes is classified within Level 3 of the fair value hierarchy, using the inputs below to calculate the fair value. The Company used a probability-weighted scenario analysis to determine the fair value of the convertible notes. The risk-free rate used in the analysis is based on the yield on a US Government zero-coupon bond, interpolated for the period that corresponds to the time to liquidity as at the valuation date.

	September 30, 2024	December 31, 2023
Adjusted Interest rate	4.38% to 4.93%	4.87% to 5.50%
Time to Financing Date	3 – 4 months	8 – 10 months

9. Common stock and Preferred Stock

Authorized Capital

The Company had been authorized to issue 20,000,000 shares of common stock, $0.001 par value per share, and 15,000,000 shares of preferred stock, $0.001 par value per share. In June 2024, the number of authorized shares of preferred stock increased to 16,000,000 shares.

Preferred stock

During the nine months ended September 30, 2024, the Company issued 432,041 shares of Series D preferred stock in connection with a CRO contract (see Note 13) and 111,616 upon conversion of debt (see Note 8).

As of September 30, 2024, and December 31, 2023, the Company has issued the following preferred stock:

Series	Number of shares issued as of September 30, 2024	Number of shares issued as of December 31, 2023	Conversion Price	Aggregate Liquidation Preference as of September 30, 2024	Aggregate Liquidation Preference as of December 31, 2023
Series seed	1,078,560	1,078,560	$0.83	$ 1,314,718	$ 1,260,811
Series A	2,592,080	2,592,080	$1.22	4,608,589	4,419,626
Series B	965,200	965,200	$2.47	3,481,589	3,338,836
Series B-1	1,480,560	1,480,560	$2.47	5,340,553	5,121,578
Series C	4,432,880	4,432,880	$2.64	17,105,642	16,404,271
Series C-1	530,040	530,040	$2.64	2,045,324	1,961,461
Series D	4,224,097	3,680,440	$3.89	22,674,382	20,086,235
Total	15,303,417	14,759,760		**$56,570,796**	**$52,592,818**

The significant terms of the preferred stock, are as follows:

Preferred stock carries an 8% cumulative preference dividend, payable when declared by the Board of Directors. No dividend has been paid on any series of preferred stock as of September 30, 2024. As of September 30, 2024, and December 31, 2023, cumulative dividends in arrears for all classes' preferred shares were approximately $17,289,000 and $14,991,000, respectively.

Each share of preferred stock shall be convertible at the option of the holder, without the payment of additional consideration, into units of common stock at the conversion price as defined in the shareholders' agreement. The conversion price is subject to adjustment in the event of subsequent issuance of common stock at a lower price than the original conversion price. Each series preferred stock is mandatorily convertible into common stock at the conversion price as defined in the shareholders' agreement on the occurrence of an initial public offering (IPO').

In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, all classes of preferred stockholders would be entitled to receive, in preference to common shareholders, an amount equal to the original issue price plus accrued and unpaid dividends. All series of preferred stock rank pari passu with each other in terms of liquidation preference except series B1 and C1. Part of the amount invested by series B1 and C1 preferred stock as mentioned in the shareholders' agreement ranks junior to other preferred stockholders, however, rank pari passu with each other. After the liquidation preference payments to all classes of preferred stockholders have been met, preferred shareholders have unlimited right to participate on a prorated basis with common shareholders.

Holders of the preferred stock shall be entitled to elect 5 members of the Board of Directors and also hold certain protective rights with respect to significant corporate transactions as defined. Each holder of common stock shall be entitled to one vote in respect of each share held.

10. Stock-Based Compensation

On December 14, 2018, the Company authorized an Employee Stock Option Plan 2018 ('ESOP plan') under which 1,719,720 shares of common stock were reserved/authorized by the Company for issuance to directors, consultants, and employees of the Company. The ESOP plan entitles directors, consultants, and employees of the Company to purchase common stock for each option of the Company at a stipulated price, subject to compliance with vesting conditions i.e. employees remaining in employment during the vesting period and director and consultants to continue rendering services during the vesting period. The options of directors and consultants vest as per the schedule prescribed in the grant letter. These can be exercised any time after the vesting period and during their tenure with the Company. However, the exercise period lapses ninety (90) days after the employee, director or consultant leaves the Company.

The Company recognized $ Nil and $ Nil of stock-based compensation expense (which is included in research and development expenses) in the Company's Consolidated Statements of Operations and Comprehensive loss for the nine months ended September 30, 2024, and 2023, respectively.

The fair value of stock-based compensation transactions is measured using the Black-Scholes option pricing model. Measurement inputs include share price on the measurement date, the exercise price of the instrument, expected volatility (based on weighted average historic volatility for a duration equal to the weighted average life of the instruments, life based on the average of the vesting and contractual periods for employee awards as minimal prior exercises of options in which to establish historical exercise experience), and the risk-free interest rate (based on government bonds). Service and performance conditions attached to the transactions, if any, are not considered in determining fair value. The expected life of the stock options is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the options is indicative of future trends, which may also not necessarily be the actual outcome. The Company is a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical data regarding the volatility of a publicly traded set of peer companies. The expected term of stock options granted to non-employees is between 5 and 7 years. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Stock-based compensation expense attributable to equity awards granted to employees is measured at the grant date based on the fair value of the award. The expense is recognized on a straight-line basis over the requisite service period for awards that vest, which is generally the period from the grant date to the end of the vesting period. Stock-based awards provided to non-employees are measured and expensed as the services are provided and are remeasured at each reporting period until these stock options vest. There were no stock options granted in 2023. In June 2024, the Company granted options to purchase 643,040 shares of common stock in settlement of accrued compensation (see Note 7). There was no expense recorded for these stock option grants since these were issued in lieu of previously recognized compensation.

The Company has estimated the fair value of the 2024 stock option awards as of the date of grant by applying the Black-Scholes option-pricing model. In applying the Black-Scholes option pricing model, the Company used the following assumptions:

Risk- free interest rate	5.2%
Expected term	5 years
Expected volatility	76%
Expected dividends	0
Grant date fair value of common stock	$0.90

The summary of stock options activity for the nine months ended September 30, 2024, and the year ended December 31, 2023, is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Time to Expiry
Outstanding as of December 31, 2022	1,101,600	$0.69	5.7 years
Granted during the year	—		
Exercised during the year	—		
Expired during the year	(288,880)	1.07	
Outstanding as of December 31, 2023	812,720	$0.55	4.7 years
Granted during the nine months ending September 30, 2024	643,040	$0.90	9.7 years
Exercised during the Nine months ending September 30, 2024	—		
Outstanding as of September 30, 2024	1,455,750	$0.71	6.7 years
Exercisable as of September 30, 2024	1,455,750	$0.71	6.7 years

The following outlines the outstanding and vested stock options by exercise price at December 31, 2023.

Exercise price	Number of options outstanding	Number of options vested
$0.48	700,720	700,720
$1.00	112,000	112,000
Total	**812,720**	**812,720**

The following outlines the outstanding and vested stock options by exercise price as of September 30, 2024.

Exercise price	Number of options outstanding	Number of options vested
$0.48	700,720	700,720
$0.90	643,030	643,090
$1.00	112,000	112,000
Total	**1,455,750**	**1,455,750**

As of September 30, 2024, there is no future compensation cost to be recognized in the Consolidated Statements of Operations and Comprehensive Loss related to stock options granted through September 30, 2024. The intrinsic value of vested and outstanding stock options was approximately $429,000.

11. Income taxes

Both VTI and VTL generated a current taxable loss for the nine months ended September 30, 2024, and 2023, and therefore the only current income taxes payable were certain minimum taxes. The effective tax rate for the years ended September 30, 2024, and 2023 was NIL and differs from the federal statutory income tax rate of 21% principally due to the full valuation allowance recognized against deferred income tax assets, and to a lesser extent due to different tax rates in the jurisdiction of VTL and certain non-deductible expenses for income tax purposes.

Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carryforwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company

has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carryforward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance. As of December 31, 2023, VTI has net operating loss carry-forwards of approximately $15,700,000 in the United States which shall expire as follows: $3.8 million has no expiry, $10.2 million expiry in 2039, and $1.7 million expiry in 2038.

12. Leases

The Company leases offices and laboratory space in India under a one-year lease terminating in December 2024, with a monthly rental payment that ranges from approximately $2,000 to $4,000 per month. From September 2021 through December 2022, the landlord did not charge the Company for contractual rent escalations. The leases were extended for a one-year period ending December 2024 with monthly payments ranging from $2,500 to $2,900 per month. The Company has an intention to renew the leases for the two additional years allowed under the lease agreement.

Operating leases are presented in the Company's consolidated balance sheets as right-of-use assets from leases, current lease liabilities, and long-term lease liabilities. The assets and liabilities from our leases are recognized at the lease commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates. Short-term leases, which have an initial term of 12 months or less, are not recorded on the balance sheet. As the Company's operating leases do not provide implicit rates, the Company has utilized its incremental borrowing rate, determined based on the long-term borrowing costs of companies with similar credit profiles, to record its lease obligations. For operating leases, the Company recognizes the minimum rental expense on a straight-line basis based on the fixed components of a lease arrangement. The Company will amortize this expense over the term of the lease beginning with the lease commencement date.

If the Company renews the lease for the entire three-year period, as expected, the annual lease payments will be approximately $30,000, $32,000, and $35,000 in the years ending December 31, 2024, 2025 and 2026, respectively. The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of September 30, 2024, and 2023:

Lease payments – From September 2024 to December 2024	$ 7,522
Lease payments – 2025	32,345
Lease payments – 2026	34,771
Total undiscounted operating lease payments	$74,639
Less: Imputed interest	(6,238)
Present value of operating lease liabilities	$68,402
Current portion of lease liability	$27,498
Long-term portion of lease liability	40,904
Total lease liability	$68,402

	As of September 30, 2024	As of December 31, 2023
Weighted average remaining lease term in years	2.7	3.0
Weighted average discount rate	8.0%	8.0%

The Right of Use Asset on September 30, 2024, of $67,922 will be amortized over the three-year remaining under the lease term.

The Right of Use Asset balance on December 31, 2023, was $87,060. Rent expenses were approximately $ 42,325 and $ 39,197 for the years ended September 30, 2024, and 2023 respectively. In the U.S., the Company has month-to-month shared space arrangements.

13. Commitments and contingencies

CRO contract

In December 2018, the Company entered into an agreement with a Contract Research Organization ("CRO") for services to be rendered with respect to the phase 2B clinical trials for the VB-1953 product. During 2022, the Company and the CRO signed a definitive agreement to convert the liability of $1,680,210 into shares of 432,041 shares of Series D preferred shares(based upon the then estimated fair value of such shares), however, the shares were not issued. The Company was required to authorize additional Series D preferred shares in order to consummate this transaction, and accordingly, as of December 31, 2023, $1,680,210 was recorded as a liability to be settled in equity in the consolidated balance sheet. In June 2024, the Company increased its authorized shares of preferred stock and issued 432,041 shares of Series D preferred stock to settle this liability.

Employee Benefits — Gratuity

The Company has a defined benefit gratuity scheme for its employees in India. This gratuity scheme provides for lump sum payment in accordance with the provisions of the Payment of Gratuity Act, 1972 to vested employees at retirement or death while in employment or on termination of employment of an amount equivalent to 15 days basic salary payable for each completed year of service or part thereof in excess of nine months subject to a limit of INR 1,000,000 (equivalent to approximately $12,000). Vesting occurs upon completion of 5 years of continuous service. A roll forward of the liability balance for the nine months ended September 30, 2024, and 2023 are as follows:

	Nine months ending September 30, 2024	Nine months ending September 30, 2023
Obligation recognized in balance sheet:		
Beginning of the nine months	$ 79,854	$ 78,224
Benefits paid	(12,366)	(15,341)
Expenses charged to profit or loss	598	21,896
Currency translation differences	(621)	(405)
End of the nine months	$ 67,465	$ 84,375

Employee Benefits — Leave Encashment

Accumulated Compensated absences or paid leave encashment, which are expected to be encashed within 12 months from the end of the year and are treated as short-term employee benefits. The obligation towards the same is measured at the expected cost of accumulating compensated absences as the additional amount expected to be paid as a result of the unused entitlement at the end of the year. Actuarial gains or losses are recognized in the Consolidated Statement of Operations and Comprehensive Loss in the year in which they arise. A roll forward of the liability balance for the Nine months ended September 30, 2024, and 2023 are as follows:

	Nine months ending September 30, 2024	Nine months ending September 30, 2023
Obligation recognized in balance sheet:		
Beginning of the nine months	$84,647	$83,724
Benefits paid	(3,889)	(8,480)
Expenses charged to profit or loss	(1,869)	13,031
Currency translation differences	(625)	(393)
End of the nine months	$78,264	$87,882

Employee Benefits — Provident Fund

In accordance with Indian law, all employees in India are entitled to receive benefits under the 'Provident Fund', which is a defined contribution plan. Both the employee and the employer make monthly contributions to the plan at a predetermined rate (presently at 12%) of the employee's basic salary. These contributions are made to the fund which is administered and managed by the Government of India. The Company's monthly contributions to the above-mentioned plans are charged to consolidated statements of operations loss in the year they are incurred and there are no further obligations under the plan beyond those monthly contributions. The Company's contribution towards the Provident Fund during the nine months ended September 30, 2024, and 2023 was approximately $1,192 and $1318, respectively.

Litigation

From time to time, the Company is involved in various disputes, claims, liens and litigation matters arising out of the normal course of business which could result in a material adverse effect on the Company's combined financial position, results of operations or cash flows. Liabilities for loss contingencies arising from claims, assessments, litigation, fines and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated. As of September 30, 2024, and December 31, 2023, the Company had no outstanding claims or litigation and had no liabilities recorded for loss contingencies.

14. Segments

The Company operates in two segments — the sale of products and licensing/service income in India ("Pharmaceutical Segment") and the development of biotechnology products ("Biotechnology Segment"), with substantially all of the resources of the Company focused on its biotechnology activities. The Company purchases substantially all of the products for the Pharmaceutical Segment from a third-party manufacturer. Other income items relate to corporate financing activities outside of these two segments. Reporting by segment is summarized as follows:

	For the nine month period ending September 30, 2024			For the nine month period ending September 30, 2023		
Amount in USD	**Biotechnology**	**Pharmaceutical**	**Total**	**Biotechnology**	**Pharmaceutical**	**Total**
Revenues	$ —	$ 195,516	$ 195,516	$ —	$ 346,571	$ 346,571
Gross margin	**—**	**195,516.00**	**195,516.00**	**—**	**213,330.00**	**$ 213,330**
Operating expenses						
Depreciation and amortization	13,483.00		13,483.00	14,420.00	—	14,420.00
SGA & R&D	879,903.80	103,077.20	982,981.00	783,370.59	121,726.41	860,097.00
Total Operating expenses	**$ 893,387**	**$ 103,077**	**$ 996,464**	**$ 752,791**	**$ 121,726**	**$ 874,517**
Other expenses						
Interest expense	153,229.00		153,229.00	(22.00)		121,409.00
Significant Non cash items	17,996.00		17,996.00	(21.00)		(327,773.00)
Unusual Items	(2,341.00)		(2,341.00)	(23.00)		1,759.00
Other expenses	**$ 168,884**	**$ —**	**$ 168,884**	**$ (66)**	**$ —**	**$ (204,605)**
Segment income/loss before tax	$ (1,062,271)	$ 92,439	$ (969,832)	$ (752,725)	$ 91,604	$ (456,582)
Income tax	—	—	—	—	—	—
Net income	**$ (1,062,271)**	**$ 92,439**	**$ (969,832)**	**$ (752,725)**	**$ 91,604**	**$ (456,582)**
Asset	$ 1,353,968	$ 348	$ 1,354,316	$ 1,409,063	$ 80,344	$ 1,489,407

The Company derives revenues from the sale of products, including royalties related to sales of such products and from the license of technology. Substantially all revenues for the nine months ended September 30, 2024, and 2023 are derived from one customer, a significant pharmaceutical company based in India ("Major Customer"). Revenues for the nine months ended September 30, 2024, and 2023 are summarized as follows:

	Nine months ending September 30, 2024	Nine months ending September 30, 2023
Sale of Dandruff Lotion and Shampoo Trading	—	$221,449
Licensing and milestone fees	—	121,000
Service fee for arrangements for sale of Dandruff products	187,389	—
Royalty income related to above product sales	8,127	4,022
Total	$195,516	$346,571

In December 2020, the Company entered into a licensing contract for a product to such a Major Customer, whereby the Company would be entitled to development and sales-based milestones and royalties on future sales of the product by the Major Customer. In 2021, the Company received $98,490 as a product development milestone payment which was recognized as revenue, as the development process was completed at that time. No sales-based milestones or royalties have been received under this license through December 31, 2023.

During 2023, the Company amended its arrangement with the Major Customer such that the Company will no longer be responsible for purchasing and selling inventory of the Dandruff Lotion and Shampoo, but instead will receive a net service fee payment for sales of such products made by the Major Customer. These payments are recorded as service fee revenue in the period earned.

15. Due to affiliates

The Company incurred consultancy charges to certain members of the Board of Directors of the Company ("Directors") recognized as selling, general and administrative expenses in the consolidated statements of operations amounting to approximately $75,000 and $75,000 for the nine months ended September 30, 2024, and 2023, respectively. The amount outstanding to such Directors as of September 30, 2024, and December 31, 2023, is approximately $75,000 and $450,000, respectively, which is included in the due to affiliates in the consolidated balance sheet.

The Company incurred compensation expenses to the Chief Executive Officer of the Company ("CEO") recognized as selling, general and administrative expenses in the Consolidated Statements of Operations and Comprehensive Loss amounting to approximately $195,000 for the nine months ended September 30, 2024, and 2023. The amount outstanding as of the end of September 30, 2024, and December 31, 2023, to the CEO is $160,298 and $651,298, respectively, which is included in Salary and Employment benefits Payable in the Consolidated Balance Sheets. See also Note 7 for the settlement of a portion of the salary payable.

Certain Directors have provided short-term advances to the Company from time to time, amounting to $22,831 as of September 30, 2024. This is included in due to affiliates in the accompanying Consolidated Balance Sheets and was yet to be repaid as of the date of these financial statements.

16. Subsequent events

For the consolidated financial statements as at and for the nine months ended September 30, 2024, we have evaluated subsequent events through the date the consolidated financial statements were available to be issued and determined that there have been no events that have occurred that would require adjustments to our disclosures in the consolidated financial statements.

Up to 1,779,360 Units, Each Unit Consisting of One Share of Common Stock or One Pre-funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock
Up to 1,779,360 Shares of Common Stock Underlying the Pre-Funded Warrants
Up to 14,400,005 Shares of Common Stock Underlying the Warrants

RESHAPE LIFESCIENCES INC.

PRELIMINARY PROSPECTUS

Maxim Group LLC

, 2025

PART II — INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of our common stock being registered. All the amounts shown are estimates except the SEC registration fee.

	Amount to be paid
SEC registration fee	$ 1,727
Accounting fees and expenses	$100,000
Legal fees and expenses	$100,000
Miscellaneous fees and expenses	$ 25,000
Total	$226,727

Item 14. Indemnification of Directors and Officers

General Corporation Law of the State of Delaware

Section 145(a) of the DGCL provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

Section 145(b) of the DGCL states that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which the person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the Delaware Court of Chancery or such other court shall deem proper.

Section 145(c) of the DGCL provides that to the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

Section 145(d) of the DGCL states that any indemnification under subsections (a) and (b) of Section 145 (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth in subsections (a) and (b) of Section 145. Such determination shall be made with respect to a person who is a director or officer at the time of such determination (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion or (4) by the stockholders.

Section 145(f) of the DGCL states that the indemnification and advancement of expenses provided by, or granted pursuant to, the other subsections of Section 145 shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office.

Section 145(g) of the DGCL provides that a corporation shall have the power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against such person and incurred by such person in any such capacity or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of Section 145.

Section 145(j) of the DGCL states that the indemnification and advancement of expenses provided by, or granted pursuant to, Section 145 shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director or officer, except for liability for any breach of the director's or officer's duty of loyalty to the corporation or its stockholders, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, for unlawful payments of dividends or unlawful stock purchases or redemptions in the case of a director, for any transaction from which the director or officer derived an improper personal benefit, or in any action by or in the right of the corporation in the case of an officer.

Charter

As permitted by the DGCL, our charter contains provisions that eliminate the personal liability of its directors for monetary damages for any breach of fiduciary duties as a director, except liability for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL (regarding unlawful dividends and stock purchases); or
- any transaction from which the director derived an improper personal benefit.

Bylaws

As permitted by the DGCL, our bylaws provide that:

- we are required to indemnify our directors and executive officers to the fullest extent permitted by the DGCL, subject to very limited exceptions;
- we may indemnify its other employees and agents as set forth in the DGCL;

- we are required to advance expenses, as incurred, to our directors and executive officers in connection with a legal proceeding to the fullest extent permitted by the DGCL, subject to very limited exceptions; and
- the rights conferred in the restated bylaws are not exclusive.

Indemnification Agreements

We have entered into indemnification agreements with each of our current directors and executive officers to provide these directors and executive officers additional contractual assurances regarding the scope of the indemnification set forth in our charter and bylaws and to provide additional procedural protections. There is no pending litigation or proceeding involving a director or executive officer of ReShape for which indemnification is sought. The indemnification provisions in our charter, bylaws and the indemnification agreements to be entered into between us and each of our directors and executive officers may be sufficiently broad to permit indemnification of our directors and executive officers for liabilities arising under the Securities Act.

Insurance Policies

We have director and officer insurance providing for indemnification for our directors and officers for certain liabilities, and such insurance provides for indemnification of our directors and officers for liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities

Other Sales of Unregistered Securities

- On January 19, 2021, ReShape and Armistice entered into an amendment to the Credit Agreement pursuant to which ReShape borrowed an additional $1.0 million. As an inducement to Armistice to enter into the amendment and make the additional loan contemplated thereby, ReShape issued to Armistice a warrant to purchase an aggregate of 345 shares of ReShape's common stock, with an exercise price per share equal to $10,150.00. The warrant was issued in reliance on the exemption from registration contained in Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder as transactions by an issuer not involving any public offering.
- On June 28, 2021, ReShape entered into a warrant exercise agreement with existing accredited investors to exercise certain outstanding warrants to purchase up to an aggregate of 2,735 shares of ReShape's common stock. In consideration for the immediate exercise of the warrants for cash, the exercising holders received new unregistered warrants to purchase up to an aggregate of 2,051 shares (equal to 75% of the shares of common stock issued in connection with the exercise) of ReShape's common stock in a private placement pursuant to Section 4(a)(2) of the Securities Act. The investors paid a cash purchase price for the new warrants equal to $272.02 per share of common stock underlying the new warrants. In connection with the exercise, ReShape also agreed to reduce the exercise price of certain of the existing warrants to $17,400, which was equal to the most recent closing price of ReShape's common stock on The Nasdaq Capital Market prior to the execution of the warrant exercise agreement.

  The new warrants were exercisable immediately upon issuance at an exercise price of $17,400 per share and have a term of exercise equal to five years. ReShape agreed to file a resale registration statement on Form S-3 within 30 days with respect to the new warrants and the shares of common stock issuable upon exercise of the new warrants. The warrant exercise agreement and the new warrants each include a beneficial ownership limitation that prevents any of the investors from owning more than 9.99% of ReShape's outstanding common stock at any time.

  The gross proceeds to ReShape from the exercise and the sale of the new warrants was approximately $46 million, prior to deducting placement agent fees and estimated offering expenses. ReShape used approximately $10.8 million of the net proceeds to repay in full the outstanding principal and accrued interest under its secured credit agreement dated March 25, 2020, as amended. ReShape intends to use the remainder of the net proceeds for working capital and general corporate purposes.

Maxim Group LLC acted as the exclusive placement agent for the exercise. Pursuant to an amendment, dated June 28, 2021, to its existing engagement agreement with Maxim, ReShape has agreed to pay Maxim an aggregate cash fee equal to 7.0% of the gross proceeds received by ReShape from the exercise and the sale of the new warrants and certain other expenses.

- On July 16, 2021, ReShape entered into an exchange agreement with existing institutional investors to exchange certain outstanding warrants for shares of common stock and new warrants to purchase common stock. The investors held common stock purchase warrants issued by ReShape prior to the merger of Obalon Therapeutics, Inc. and ReShape Lifesciences Inc. The merger constituted a fundamental transaction under the exchange warrants and, as a result thereof, pursuant to the terms and conditions of the exchange warrants, the investors were entitled to a cash payment equal to the Black Scholes value of the exchange warrants, calculated in accordance with the terms of the exchange warrants (the "Black Scholes Payment").

  Subject to the terms and conditions set forth in the exchange agreement and in reliance on Section 3(a)(9) of the Securities Act, in lieu of the Black Scholes Payment, ReShape and the investors agreed to exchange all of the exchange warrants for (a) a total of 202 shares of common stock, which was calculated by dividing the Black Scholes Payment by $11,710.2, which was equal to 95% of the closing market price of ReShape's common stock on The Nasdaq Capital Market on July 16, 2021 and (b) new warrants to purchase up to a total of 136 shares of common stock at an exercise price equal to $11,710.20 with a term of five years.

- On June 16, 2022, ReShape entered into a warrant exercise agreement with an existing accredited investor to exercise certain outstanding warrants to purchase up to an aggregate of 1,290 shares of ReShape's common stock. In consideration for the immediate exercise of the existing warrants for cash, the exercising holders received new unregistered warrants to purchase up to an aggregate of 1,290 shares (equal to 100% of the shares of common stock issued in connection with the exercise) of ReShape's common stock in a private placement pursuant to Section 4(a)(2) of the Securities Act. In connection with the exercise, ReShape also agreed to reduce the exercise price of the existing warrants and 555 remaining unexercised warrants from $17,400.00 to $1,933.14 per share, which is equal to the most recent closing price of ReShape's common stock on The Nasdaq Capital Market prior to the execution of the warrant exercise agreement.

  The new warrants were exercisable immediately upon issuance at an exercise price of $1,933.14 per share and have a term of exercise equal to seven and one-half years. ReShape agreed to file a resale registration statement on Form S-3 within 30 days with respect to the new warrants and the shares of common stock issuable upon exercise of the new warrants. The warrant exercise agreement and the new warrants each include a beneficial ownership limitation that prevents the investor from owning more than 4.99% of ReShape's outstanding common stock at any time.

  The gross proceeds to ReShape from the exercise was approximately $2.5 million, prior to deducting warrant inducement agent fees and estimated offering expenses. ReShape intends to use the remainder of the net proceeds for commercial growth, working capital and general corporate purposes.

  Maxim acted as the exclusive warrant inducement agent and financial advisor to ReShape for the exercise. ReShape agreed to pay Maxim an aggregate cash fee equal to 7.0% of the gross proceeds received by ReShape from the exercise.

- On November 8, 2022, ReShape entered into a securities purchase agreement with a certain institutional investor, pursuant to which ReShape agreed to issue and sell to the investor in a registered direct offering (the "Registered Offering") (i) 826 shares of our common stock, (ii) 2,500 shares of the Company's Series D Mirroring Preferred Stock, par value $0.001 per share and stated value of $0.001 per share (the "Series D Preferred Stock"), and (iii) pre-funded warrants to purchase an aggregate of 170 shares of common stock. Each share of common stock was sold at a price of $754.00 per share, each share of Series D Preferred Stock was sold a price of $0.001 per share, and each pre-funded warrant was sold at an offering price of $751.00 per share underlying such pre-funded warrants, for aggregate gross proceeds of $750,000 before deducting the placement agent's fees and the offering expenses.

Under the securities purchase agreement, ReShape also agreed to issue and sell to the investor in a concurrent private placement warrants to purchase an aggregate of 1,845 shares of common stock. The warrants have an exercise price of $1,933.14 per share, will be exercisable six months following the date of issuance, and will expire five years following the initial exercise date.

Maxim acted as the exclusive placement agent in connection with the offering and received a cash fee equal to 7.0% of the gross proceeds received by ReShape from the sale of the securities in offering, as well as reimbursement for certain expenses, and warrants to purchase up to 50 shares of common stock, which is equal to 5.0% of the aggregate amount of shares of common stock (or common stock equivalents in the form of pre-funded warrants) issued in the offering, at an exercise price of $870.00 per share.

The warrants to purchase an aggregate of 995 shares of common stock were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder and, along with the shares of common stock issuable upon the exercise of such warrants, have not been registered under the Securities Act, and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from such registration requirements. The securities were offered only to an accredited investor.

- On April 20, 2023, ReShape entered into a Securities Purchase Agreement with a certain institutional investor, pursuant to which ReShape agreed to issue and sell to the investor in a registered direct offering (i) 5,025 shares of our common stock and (ii) pre-funded warrants to purchase an aggregate of 8,782 shares of common stock. Each share of common stock was sold at a price of $178.06 per share and each pre-funded warrant was sold at an offering price of $178.00 per share underlying such pre-funded warrants, for aggregate gross proceeds of approximately $2.46 million before deducting the placement agent's fees and the offering expenses. Under the Securities Purchase Agreement, the Company also agreed to issue and sell to the investor in a concurrent private placement warrants to purchase an aggregate of 13,806 shares of common stock.

  In connection with the offering, ReShape also agreed that certain existing warrants to purchase up to an aggregate of 2,839 shares of common stock that were issued to the Investor, at an exercise price of $870.00 per share, were amended effective upon the closing of the offering so that the amended warrants have an exercise price of $178.06. ReShape's exclusive placement agent in connection with the offering, Maxim Group LLC, received a cash fee equal to 7.0% of the gross proceeds received by ReShape from the sale of the securities in offering, as well as reimbursement for certain expenses, and warrants to purchase up to 691 shares of common stock, which is equal to 5.0% of the aggregate amount of shares of common stock (or common stock equivalents in the form of pre-funded warrants) issued in the offering, at an exercise price of $196.04 per share. The offering closed on April 24, 2023.

- On November 21, 2023, ReShape entered into a warrant exercise agreement with an existing accredited investor to exercise certain outstanding warrants to purchase up to an aggregate of 92,802 shares of our common stock. In consideration for the immediate exercise of the existing warrants for cash, the exercising holders received new unregistered warrants to purchase up to an aggregate of 185,604 shares (equal to 200% of the shares of common stock issued in connection with the exercise) of our common stock in a private placement pursuant to Section 4(a)(2) of the Securities Act. In connection with the exercise, ReShape also agreed to reduce the exercise price of the existing warrants from $14.52 to $13.34 and to reduce the exercise price of the remaining unexercised warrants from either $19.14 or $14.52 to $13.34 per share, which was equal to the most recent closing price of our common stock on the Nasdaq Capital Market prior to the execution of the warrant exercise agreement.

  The new warrants became exercisable six months after issuance at an exercise price of $13.34 per share and have a term of exercise equal to five and one-half year. ReShape agreed to file a resale registration statement on Form S-3 within 30 days with respect to the new warrants and the shares of our common stock issuable upon exercise of the new warrants and to hold a meeting of its stockholders to seek approval of the potential reduction of the exercise price of the new warrants on the terms set forth in the new warrants. The existing warrants and the new warrants each include a

beneficial ownership limitation that prevents the investor from owning more than 9.99%, with respect to the existing warrants, and 4.99%, with respect to the new warrants, of our outstanding common stock at any time. Maxim Group LLC acted as the exclusive warrant inducement agent and financial advisor to the company for the exercise. ReShape agreed to pay Maxim an aggregate cash fee equal to 6.5% of the gross proceeds received from the exercise.

- On July 8, 2024, simultaneously with the execution of the Merger Agreement, ReShape, Vyome and Vyome India entered into agreements with certain existing accredited investors, pursuant to which the investors have agreed to purchase up to $7.3 million in securities of ReShape, Vyome and Vyome India. ReShape and the investors are executing and delivering the subscription agreements in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act and contemporaneously with the sale of the shares of common stock will execute and deliver a registration rights agreement in substantially the form attached to the subscription agreement.
- In a private transaction, on October 16, 2024, we entered into a securities purchase agreement (the "SPA") with Ascent. Pursuant to the SPA, we agreed to issue to Ascent a senior secured convertible note in the aggregate original principal amount of $833,333.34 (the "Note"), and also issued to Ascent 7,983 shares of common stock as "commitment shares" to Ascent. On January 14, 2025, we entered into an amendment to the Note with Ascent to (a) extend the maturity date to the earlier of the closing of the Company's merger with Vyome or 90 days after the date of the amendment, (b) provide that Ascent would not be obligated to convert any part of the Note at the closing of the merger, (c) reduce the mandatory prepayment provision for funds raised by the Company in subsequent financings from 66% to 50%, and (d) require a $45,000 cash extension fee to be paid by the Company at the maturity of the Note.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

Exhibit	Description
1.1**	Form of Placement Agent Agreement
2.2	Agreement and Plan of Merger, dated as of January 19, 2021, by and among Obalon Therapeutics, Inc. Optimus Merger Sub, Inc., and the Company (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on January 20, 2021).
2.3	Agreement and Plan of Merger, dated as of July 8, 2024, by and among ReShape Lifesciences Inc., Vyome Therapeutics, Inc., and Raider Lifesciences Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2024).
2.4	Asset Purchase Agreement, dated as of July 8, 2024, by and between ReShape Lifesciences Inc. and Ninjour Health International Limited (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2024).
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to Obalon's Registration Statement on Form S-1, filed with the SEC on September 26, 2016).
3.2	Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Obalon's Current Report on Form 8-K, filed with the SEC on June 14, 2018).
3.3	Certificate of Second Amendment to the Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Obalon's Current Report on Form 8-K, filed with the SEC on July 24, 2019).
3.4	Third Amendment to the Amended and Restated Certificate of Incorporation of ReShape (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on June 15, 2021).
3.5	Fourth Amendment to the Amended and Restated Certificate of Incorporation of ReShape (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on June 15, 2021).
3.6	Fifth Amendment to the Amended and Restated Certificate of Incorporation of ReShape (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on December 28, 2022).
3.7	Sixth Amendment to Restated Certificate of Incorporation, as amended, of ReShape Lifesciences Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on September 24, 2024).
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K filed with the SEC on June 15, 2021).
3.9	Amended and Restated Bylaws, effective as of January 16, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on January 18, 2024).
4.1	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Company's Registration Statement on Form S-1 filed with the SEC on February 3, 2023).
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on January 27, 2023).
4.3	Form of Underwriters' Warrant (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on January 27, 2023).
4.4	Form of Warrant Agency Agreement between the Company and American Stock Transfer & Trust Company, LLC (incorporated by reference to Exhibit 4.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on January 27, 2023).
4.5	Form of Common Stock Purchase Warrant and form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on April 26, 2023).

Exhibit	Description
4.6	Form of Common Stock Purchase Warrant and form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on April 26, 2023).
4.7	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2023).
4.8	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to Amendment No. 2 to the Company's Registration Statement on Form S-1 filed with the SEC on September 27, 2023).
4.9	Form of Placement Agent's Common Stock Purchase Warrant issued October 3, 2023 (incorporated by reference to Exhibit No. 4.3 to the Company's Current Report on Form 8-K filed with the SEC on October 5, 2023).
4.10	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 14, 2022).
4.11	Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on November 14, 2022).
4.12	Form of New Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 23, 2022).
4.13	Form of Series A Common Stock Purchase Warrant issued November 28, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 28, 2018).
4.14	Form of Pre-Funded Common Stock Purchase Warrant issued November 28, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on November 28, 2018).
4.15	Form of Placement Agent's Common Stock Purchase Warrant issued November 28, 2018 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on November 28, 2018).
4.16	Form of Common Stock Purchase Warrant issued September 20, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 20, 2018).
4.17	Form of Placement Agent's Common Stock Purchase Warrant issued September 20, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on September 20, 2018).
4.18	Form of Common Stock Purchase Warrant issued August 3, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2018).
4.19	Form of Placement Agent's Common Stock Purchase Warrant issued August 3, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on August 2, 2018).
4.20	Form of Common Stock Purchase Warrant issued July 12, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 12, 2018).
4.21	Form of Placement Agent's Common Stock Purchase Warrant issued July 12, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on July 12, 2018).
4.22	Form of Common Stock Purchase Warrant issued June 21, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 21, 2018).
4.23	Form of Placement Agent's Common Stock Purchase Warrant issued June 21, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on June 21, 2018).
4.24	Form of Common Stock Purchase Warrant issued June 8, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on June 8, 2018).
4.25	Form of Placement Agent's Common Stock Purchase Warrant issued June 8, 2018 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on June 8, 2018).

Exhibit	Description
4.26	Form of Common Stock Purchase Warrant issued April 3, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 3, 2018).
4.27	Form of Warrant, dated August 16, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 16, 2017).
4.28	Form of Series C Warrant, dated as of July 8, 2015, by and between the Company and several accredited investors. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on July 7, 2015 (File No. 1-33818)).
4.29	Form of Warrant (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on November 5, 2015 (File No. 1-33818)).
4.30	Form of Warrant to purchase shares of Common Stock. (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed with the SEC on January 11, 2017 (File No. 333-213704)).
4.31	Form of Pre-Funded Warrant to purchase shares of Common Stock, dated December 19, 2024 (incorporated by reference to Exhibit 4.31 to the Company's Registration Statement on Form S-1 filed with the SEC on December 19, 2024).
4.32**	Form of Common Stock Warrant issued in this offering.
4.33**	Form of Pre-Funded Warrant issued in this offering.
4.34**	Form of Placement Agent Warrant issued in this offering.
5.1*	Opinion of Fox Rothschild LLP as to the validity of the securities being registered.
10.1	2022 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 20, 2022).
10.2	Second Amended and Restated 2003 Stock Incentive Plan, as amended on May 23, 2018 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 25, 2018).
10.3	Form of Securities Purchase Agreement, dated April 20, 2023, by and between ReShape Lifesciences Inc. and the Investor (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 26, 2023).
10.4	Form of Stock Option Grant Notice and Stock Option Agreement under Second Amended and Restated 2003 Stock Incentive Plan (Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 14, 2017).
10.5	Exclusive License Agreement, dated September 19, 2023, by and between ReShape Lifesciences Inc. and Biorad Medysis Pvt. Ltd. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 22, 2023).
10.6	Form of Indemnification Agreement entered into by and between ReShape and each of its executive officers and directors. (Incorporated herein by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on July 6, 2007 (File No. 333-143265)).
10.7	Employment Agreement, dated November 1, 2022, by and between ReShape and Paul F. Hickey (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the SEC on November 14, 2022).
10.8	Executive Employment Agreement, dated October 29, 2019, by and between ReShape and Thomas Stankovich (incorporated by reference to Exhibit 10.6 to the Annual Report on Form 10-K filed with the SEC on April 17, 2023).
10.9	Retention Bonus Agreement, dated August 2, 2022, between ReShape and Thomas Stankovich (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on August 2, 2022).
10.10	Lease Agreement, dated March 13, 2023, by and between The Irvine Company LLC and the Company (incorporated by reference to Exhibit 10.8 to the Annual Report on Form 10-K filed with the SEC on April 17, 2023).
10.11	Lease Agreement, entered into January 20, 2017, by and between ReShape Medical, Inc. and San Clemente Holdings, LLC (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed with the SEC on April 2, 2018).

Exhibit	Description
10.12	Warrant Exercise Agreement, dated June 16, 2022, by and among ReShape Lifesciences Inc. and the investor party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 23, 2022).
10.13	Form of Securities Purchase Agreement, dated November 8, 2022, by and between ReShape Lifesciences Inc. and the investor party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 14, 2022).
10.14	Form of Warrant Amendment Agreement, dated November 8, 2022, by and between ReShape Lifesciences Inc. and the investor party thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on November 14, 2022).
10.15	Agreement to Amend Series C Convertible Preferred Stock, dated as of July 8, 2024, by and among ReShape Lifesciences Inc. and holders of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2024).
10.16	Form of Subscription Agreement by and between ReShape Lifesciences Inc. and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2024).
10.17	Form of Voting and Support Agreement by and among ReShape Lifesciences Inc. and certain stockholders of Vyome Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2024).
10.18	Amendment to Employment Agreement, dated July 8, 2024, by and between ReShape Lifesciences Inc. and Paul F. Hickey (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2024).
10.19	Form of Securities Purchase Agreement, dated as of October 16, 2024 by and between the Company and Ascent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 17, 2024).
10.20	Form of Note, dated as of October 16, 2024 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on October 17, 2024).
10.21	Form of Registration Rights Agreement, dated as of October 16, 2024 by and between the Company and Ascent (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on October 17, 2024).
10.22	Form of Security Agreement, dated October 16, 2024 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on October 17, 2024).
10.23	Form of Guaranty, dated October 16, 2024 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on October 17, 2024).
10.24	Form of Lock-Up Agreement, dated October 16, 2024 (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the SEC on October 17, 2024).
10.25	Form of Leak-Out Agreement, dated October 16, 2024 (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the SEC on October 17, 2024).
10.26	Equity Purchase Agreement, dated as of December 19, 2024, by and between the Company and Ascent (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 20, 2024).
10.27**	Form of Securities Purchase Agreement
21.1	Subsidiaries of ReShape Lifesciences Inc. (incorporated by reference to Exhibit 21.1 to the Annual Report on Form 10-K filed with the SEC on April 1, 2024).
23.1*	Consent of Fox Rothschild LLP relating to opinion as to validity of the securities being registered (included in Exhibit 5.1 hereto).
23.2**	Consent of RSM US LLP.
23.3**	Consent of Kreit & Chiu CPA LLP.
24.1**	Power of Attorney (included on the signature page to this registration statement)
107*	Calculation of Filing Fee Table

* Filed herewith.

** Previously filed.

(b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) (§230.424(b)) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "*Calculation of Filing Fee Tables*" or "*Calculation of Registration Fee*" table, as applicable, in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (ii) and (iii) shall not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post- effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of this offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of Title 17 of the Code of Federal Regulations), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this Registration Statement, regardless of the underwriting

method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of Title 17 of the Code of Federal Regulations);

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the undersigned registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, State of California, on February 14, 2025.

RESHAPE LIFESCIENCES INC.

By: /s/ Paul F. Hickey

Name: Paul F. Hickey
Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Capacity	Date
/s/ Paul F. Hickey Paul F. Hickey	President and Chief Executive Officer and Director (Principal Executive Officer)	February 14, 2025
/s/ Thomas Stankovich Thomas Stankovich	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 14, 2025
* Dan W. Gladney	Director	February 14, 2025
* Gary D. Blackford	Director	February 14, 2025
* Lori C. McDougal	Director	February 14, 2025
* Arda M. Minocherhomjee, Ph.D.	Director	February 14, 2025

* By Paul F. Hickey, as attorney-in-fact

/s/ Paul F. Hickey
Paul F. Hickey

Exhibit 5.1

City Center
33 South Sixth Street
Suite 3600
Minneapolis, MN 55402
Tel (612) 607-7000 Fax (612) 607-7100
www.foxrothschild.com

February 14, 2025

ReShape Lifesciences Inc.
18 Technology Drive, Suite 110
Irvine, CA 92618

RE: ReShape Lifesciences Inc. Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to ReShape Lifesciences Inc., a Delaware corporation (the "**Company**"), in connection with its filing with the Securities and Exchange Commission (the "**Commission**") of a registration statement on Form S-1 (Registration No. 333-284362, as amended or supplemented from time to time, the "**Registration Statement**"), relating to the public offering by the Company (the "**Offering**") of up to 1,779,360 units (the "**Units**") of the Company, with each Unit consisting of: (i) either one share of the Company's common stock, par value $0.001 per share (the "**Common Stock**" and such shares, the "**Shares**")), or one pre-funded warrant to purchase one share of Common Stock at an exercise price equal to $0.001 per share of Common Stock (the "**Pre-Funded Warrants**" and the shares of Common Stock issuable upon exercise thereof, the "**Pre-Funded Warrant Shares**") and (ii) one warrant to purchase one and one-half shares of Common Stock (the "**Common Warrants**" and the 14,400,005 shares of Common Stock issuable upon exercise of the Common Warrants, the "**Common Warrant Shares**"). The Units are to be sold by the Company pursuant to a placement agency agreement (the "**Placement Agency Agreement**") to be entered into by and between the Company and Maxim Group, LLC, as placement agent (the "**Placement Agent**"), the form of which has been filed as Exhibit 1.1 to the Registration Statement, and a securities purchase agreement to be entered into by and between the Company and investors in the Offering, the form of which has been filed as Exhibit 10.27 to the Registration Statement (the "**SPA**"). As noted in the Registration Statement, for each Pre-Funded Warrant sold, the number of Shares sold will be decreased on a one-for-one basis.

The Units, including the Shares, Common Warrants and Pre-Funded Warrants included in the Units, and the Common Warrant Shares and Pre-Funded Warrants Shares are collectively referred to herein as the "**Securities**."

This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act of 1933, as amended (the "**Securities Act**"), and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement other than as expressly stated herein.

In connection with this opinion, we have examined the Company's Restated Certificate of Incorporation and all amendments thereto; the Company's Restated Bylaws, as currently in effect; the Registration Statement and the exhibits thereto; the prospectus contained in the Registration Statement; the form of Placement Agency Agreement; the form of SPA; the form of Common Warrant; the form of Warrant Agency Agreement; the form of Pre-Funded Warrant; and such other documents, records, certificates, memoranda and instruments as we have deemed necessary as a basis for this opinion. We have also examined the resolutions of the Board of Directors of the Company authorizing the filing of the Registration Statement by the Company and the issuance of the Securities by the Company (the "**Resolutions**").

Based upon, subject to and limited by the foregoing, we are of the opinion that following (i) execution and delivery by the Company and the Placement Agent of the Placement Agency Agreement, (ii) effectiveness of the Registration Statement, (iii) issuance of the Securities pursuant to the Resolutions and the terms of the Underwriting Agreement, the Common Warrant and the Pre-Funded Warrant, as applicable, and (iv) receipt by the Company of the consideration for the Securities:

1. The Shares will be validly issued, fully paid and non-assessable.

2. The Warrants will constitute the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, under the laws of the State of New York.

3. The Pre-Funded Warrants will constitute the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, under the laws of the State of New York.

4. The Common Warrant Shares issuable upon exercise of the Common Warrants and the Pre-Funded Warrant Shares issuable upon exercise of the Pre-Funded Warrants have been duly authorized and, when issued upon exercise of the Common Warrants and the Pre-Funded Warrants upon payment of the applicable exercise price therefor in accordance with the terms thereof, will be validly issued, fully paid and non-assessable

Our opinion herein is expressed solely with respect to the General Corporation Law of the State of Delaware (including the statutory provisions, all applicable provisions of the Delaware Constitution and reported judicial decisions interpreting the foregoing) and, solely for purposes of paragraphs 2 and 3 above, the laws of the State of New York and is based on these laws as in effect on the date hereof. We express no opinion herein as to any other statutes, rules or regulations. We express no opinion herein as to whether the laws of any jurisdiction are applicable to the subject matter hereof. We are not rendering any opinion as to compliance with any federal or other state law, rule or regulation relating to securities, or to the sale or issuance thereof. We give no opinion as to whether the Company or its beneficial owners are in compliance with the Corporate Transparency Act and/or the rules and regulations promulgated thereunder or any similar state law, rule or regulation.

This opinion letter has been prepared for your use in connection with the Offering. This opinion is expressed as of the date hereof, and we disclaim any undertaking to advise you of any subsequent changes in the facts stated or assumed herein or of any subsequent changes in applicable law.

We consent to the filing of this opinion letter as an exhibit to the Registration Statement and to the reference to this firm under the caption “Legal Matters” in the prospectus contained therein. In giving this consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Fox Rothschild LLP

Exhibit 107

Calculation of Filing Fee Tables

Form S-1
(Form Type)

RESHAPE LIFESCIENCES INC.

(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	**Security Class Title**	**Fee Calculation Rule**	**Amount Registered[1]**	**Proposed Maximum Offering Price Per Unit**	**Maximum Aggregate Offering Price[1]**	**Fee Rate**	**Amount of Registration Fee[2]**
Fees to be paid	Equity	Common stock, par value $0.001 per share	457(o)	-	-	$5,000,000	$153.10 per $1,000,000	$765.50
	Other	Pre-funded warrants to purchase common stock[3]	457(g)	-	-	-	-	-
	Equity	Common stock, par value $0.001 per share, underlying pre-funded warrants[2][4]	457(o)	-	-	-	-	-
	Other	Warrants to purchase common stock[3]	457(g)	-	-	-	-	-
	Equity	Common stock, par value $0.001 per share, underlying warrants[2]	457(o)	-	-	$40,464,014	$153.10 per $1,000,000	$6195.04
	Other	Placement agent's warrants to purchase common stock[3]	457(g)	-	-	-	-	-
	Equity	Common stock, par value $0.001 per share, underlying placement agent's warrants[2][5]	457(o)	-	-	$300,000	$153.10 per $1,000,000	$45.93
Carry Forward Securities	-	-	-	-	-	-	-	-
	Total Offering Amounts					$45,764,014	$153.10 per $1,000,000	$7006.47
	Total Fee Offsets							
	Fees Previously Paid[6]							$1730.03
	Net Fee Due							$5276.44

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416 under the Securities Act, this registration statement shall also cover any additional shares of the registrant's securities that become issuable by reason of any share splits, share dividends or similar transactions.

(3) No separate registration fee is payable pursuant to Rule 457(g) under the Securities Act. In accordance with Rule 457(i) under the Securities Act, no separate registration fee is required with respect to the warrants or pre-funded warrants registered hereby.

(4) The registrant may issue pre-funded warrants to purchase common stock in the offering. The purchase price of each pre-funded warrant will be equal to the price per share at which shares are being sold to the public in this offering, minus $0.001, which constitutes the pre-funded portion of the exercise price of the pre-funded warrants, and the remaining unpaid exercise price of the pre-funded warrants will equal $0.001 per share (subject to adjustment as provided for therein). The proposed maximum aggregate offering price of the shares will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the shares to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants issued in the offering. Accordingly, the proposed maximum aggregate offering price of the shares of common stock and pre-funded warrants is $5,000,000.

(5) Based on an assumed per share exercise price for the placement agent's warrants of 120% of the public offering price per unit in this offering.

(6) The registrant previously paid a fee of $1730.03.