UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark one)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 1-37897

VYOME HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**26-1828101**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

Harvard Square, One
Mifflin Place, Suite 400, Cambridge, MA
(Address of principal executive offices, including zip code)

(973) 832-8147
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on which Registered
Common stock, $0.001 par value per share	HIND	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

At June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock as reported by the Nasdaq on that date was $6,402,262.

As of March 17, 2026, 7,018,528 shares of the registrant's common stock were outstanding.

Documents Incorporated by Reference

None.

FORWARD-LOOKING STATEMENTS AND ASSOCIATED RISKS

All statements in this Form 10-K that do not directly and exclusively relate to historical facts constitute "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions that convey uncertainty of future events or outcomes to identify forward-looking statements.

These statements represent current expectations and beliefs, and no assurance can be given that the results described in such statements will be achieved. Such statements are subject to numerous assumptions, risks, uncertainties and other factors that could cause actual results to differ materially from those described in such statements, many of which are outside of our control. No assurance can be given that any expectation, belief, goal or plan set forth in any forward-looking statement can or will be achieved, and readers are cautioned not to place undue reliance on such statements which speak only as of the date they are made. We do not undertake any obligation to update or release any revisions to any forward-looking statement or to report any events or circumstances after the date of this Form 10-K or to reflect the occurrence of unanticipated events.

You should carefully consider these and other relevant factors, including those risk factors in Item 1A, "*Risk Factors*" of this Form 10-K and any other information included or incorporated by reference in this report, and information which may be contained in the Company's other filings with the SEC, when reviewing any forward-looking statement. Investors should understand it is impossible to predict or identify all such factors or risks. As such, you should not consider either foregoing lists, or the risks identified in the Company's SEC filings, to be a complete discussion of all potential risks or uncertainties associated with an investment in the Company.

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PART I.

ITEM 1. BUSINESS

Our Company

On August 15, 2025, ReShape Lifesciences Inc. (now known as Vyome Holdings, Inc.) (the "Company") completed the merger pursuant to the Agreement and Plan of Merger, dated as of July 8, 2024, as amended (the "Merger Agreement"), by and among the Company, Raider Lifesciences Inc., a wholly owned subsidiary of the Company ("Merger Sub"), and Vyome Therapeutics, Inc. ("Vyome"). Pursuant to the Merger Agreement, Merger Sub merged with and into Vyome, with Vyome surviving the merger as a subsidiary of the Company (the "Merger"). As a result of the Merger, the Company was renamed "Vyome Holdings, Inc." and Vyome continued under its name as Vyome Therapeutics, Inc., in each case effective before the open of trading on August 15, 2025.

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 in advanced cancer, a potential orphan drug designation program. The Company has announced positive results from a phase 2 investigator-initiated trial. The Company is planning to have discussions with the Food & Drug Administration (FDA) on a pivotal phase 3 trial design in the first half of 2026. The Company also has a Pre-Investigational New Drug application stage ophthalmic drops program, a potential 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 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. One of the agreements for the supply of dandruff products to Sun Pharma was terminated in December 2024. The Company has also entered into an agreement with Sun Pharma for the development and licensing of MRT technology-based Luliconazole topical cream for skin fungal diseases for the Indian market

The Company operates in two segments, biotechnology and pharmaceutical products. 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 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 various licensing agreements with Sun Pharma.

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 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, 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, and Venkat Nelabhotla, 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. 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 scientific approach is built on this scientific rigor and advanced technology, which, together with the learnings from a resource-poor setting, offers a powerful engine for innovation, differentiation, and cost-efficiency.

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. 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 have 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 also limit the ability of US companies to contract with biotechnology companies with ties to the Chinese government.

We have and will continue to build our team to reflect this evolving geopolitical relationship. 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 include 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 $400 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 phase 3 study for the treatment of malodor of malignant fungating wounds in advanced cancer patients. 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.

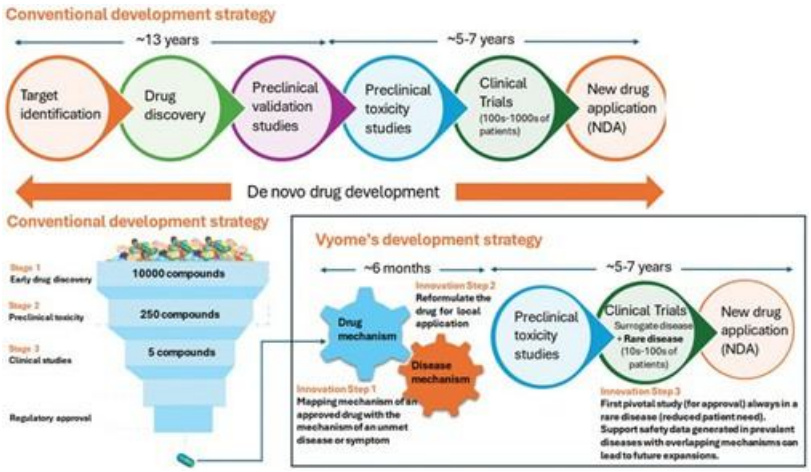
The second stage is the pre-clinical phase, where the leads identified during the early drug discovery phase are refined, optimized, and extensively tested in animal or alternative models. The aim is to provide sufficient evidence of safety and efficacy before clinical trials in humans can begin.

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, up to 25%% tax credit for clinical testing costs in the USA, and an exclusive right to market the drug for seven years after regulatory approval. Orphan drug manufacturers also receive waivers of drug application fees up to approximately $4 million 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 a longer time and require a 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

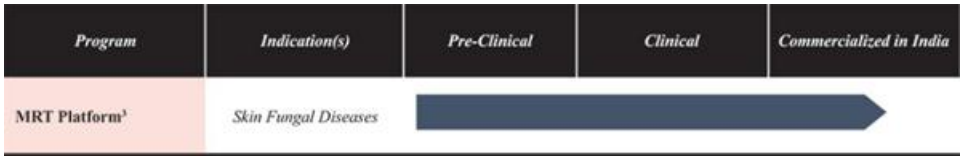
Leveraging the above strategy, we have built out a robust product portfolio (See **Figures 2.1 and 2.2**).

Figure 2.1 Pipeline for VT-1953, VT-1908 and VB-1953

(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.

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 feelings 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.

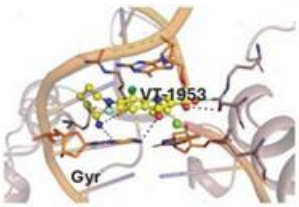
There are currently no FDA-approved treatments for MFW or for symptoms of malodorous malignant fungating wounds. Patients are managed using old obsolete, and suboptimal agents, such as metronidazole, aromatic oils, camphor, honey, or silver-coated dressings. Metronidazole is widely used topically off-label. 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 patient. 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 anaerobic 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.

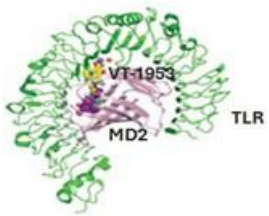
Figure 3. Mechanistic analysis of MFW symptoms

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 0.5µg/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 0.25µg/ml (MIC50=0.25µg/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 0.25µg/ 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 0.015-0.5µg/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)**.

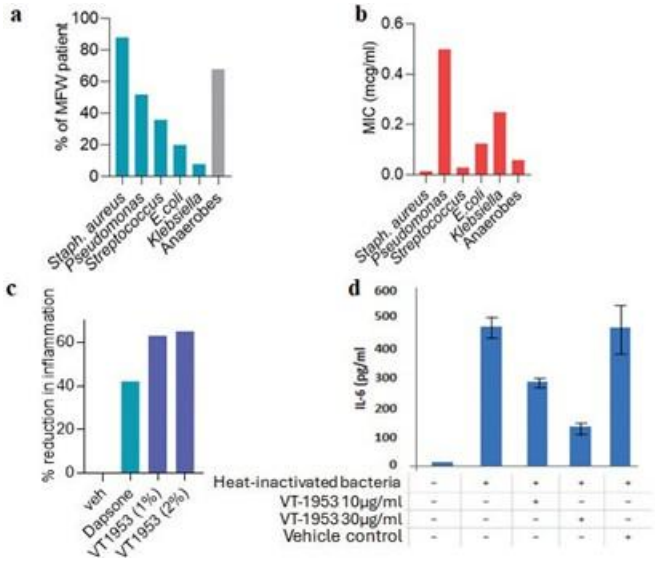
Figure 5.

(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.



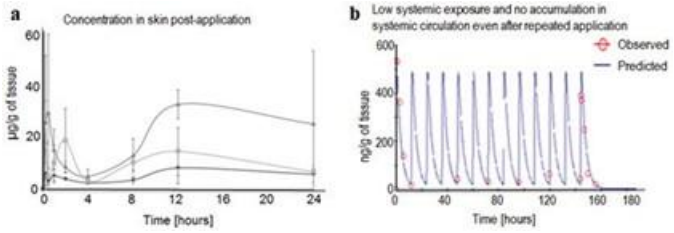
Pre-Clinical Toxicity Studies

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 VT-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 (twce daily for 7 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. The 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, the *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 the pooled vehicle 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 was also numerically superior in both treatment groups than in the pooled vehicle group. The secondary efficacy endpoints were evaluated by the percentage of the population that achieved an 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 the 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 the Pooled Vehicle (56.5%) arms at Week 12.

In conclusion, the clinical investigators noted the following in their report

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 (3) SAEs were considered not related to the study drug. Overall, the safety profile of topical VB-1953 gel and Vehicle was comparable when applied either QD or BID for 12 weeks.

(4) 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 poc ph 2 study to evaluate the safety and efficacy of VT-1953 topical gel in advanced cancer patients with malodorous malignant fungating wounds (MFW).

An investigator-initiated POC Ph 2 study to evaluate the safety and efficacy of VT-1953 (also termed as VB-1953) 2% topical gel in advanced cancer patients with malodorous malignant fungating wounds was completed in December 2025. In investigator-initiated trials (IITs), while the investigator is the sponsor of the trial, the test agent is provided by Vyome, and Vyome has the right 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 were included in this study. Subjects who were currently being treated with any antibiotic for bacterial infections or suffering from any infection that may require systemic antibiotics 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.

The trial followed a sequential recruitment design, with the first 10 patients enrolled in this study being treated with VT-1953 2% gel (also termed as VB-1953 2% gel) and the next 5 patients being treated with the vehicle (control). 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 endpoints* in this clinical study were the change in the score of malodor associated with malignant fungating wounds (scored by investigators) using a 6 point TELER Scale on Day 14 and Safety Outcome Measures, i.e. Treatment-Emergent Adverse Events (TEAEs), changes in vital signs, and severity of local skin reactions (stinging/burning, edema)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 endpoint 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. Secondary efficacy end-points included the percentage of patients who scored 3 to 5 on malodor at Day 7 and 14 using a QOL Component scale, and the score of malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at Day 7.

- Other *exploratory endpoints* include (a) Change in score of malodors associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale on Day 14 and 7 from baseline; (b) Percentage of patients who score 4,5 on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at Day 14 and 7; (c) Percentage of patients who exhibited ≥ 2-point improvement on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at Day 14 and 7; (d) Score of malodor associated with malignant fungating wounds (scored by patients) using a 10-point VAS Scale at Day 7; (e) Score of malodor associated with malignant fungating wounds (scored by patients) using a 10-point VAS Scale at Day 14; (f) Change in score of malodor associated with malignant fungating wounds (scored by patients) using a 10-point VAS Scale at Day 14 and 7; (g) Pain score associated with the wound as scored by the patient using a 10-point Visual Analog Scale on Day 7 and 14; (h) Change in pain score associated with the wound as scored by the patient using a 10-point Visual Analog Scale on Day 14 and 7; (i) Score of exudates as scored by the caregiver measured on 0-4 scale on Day 7 and 14; (j) Quality of Life (QOL) score on VAS scale at Day 7 and Day 14 as scored by the patient; and (k) Change in Quality of Life (QOL) score on VAS scale at Day 7 and Day 14 as scored by the patient.

Analysis of Safety: No significant TEAEs or safety signals or changes in vital signs were noted.

Analysis of Efficacy

Primary Endpoint: Score of malodors associated with MFW using a 6 point TELER Scale on Day 14

The primary outcome measure, the score of malodors associated with malignant fungating wounds using a 6-point TELER scale, was assessed at baseline and on Day 14. Overall, the median malodor score improved from 1.0 (0.0, 1.0) at baseline to 3.0 (1.0, 4.0) on Day 14, with a statistically significant difference between baseline and Day 14 ($p = 0.0015$). In the VT-1953 Topical Gel treatment group, the median score improved from 0.5 (0.0, 1.0) at baseline to 4.0 (3.0, 4.0) on Day 14, which was statistically significant ($p = 0.0020$). In contrast, the Vehicle Topical Gel group showed no change in median malodor score, remaining at 1.0 (1.0, 1.0) at both baseline and Day 14, with no statistically significant difference ($p > 0.9999$). The between-treatment comparison at Day 14 was statistically significant ($p=0.0015$) indicating that the VT-1953 topical gel group was superior to the Vehicle topical gel in reducing Malodor.

Table 1: Score of Malodors Associated with Malignant Fungating Wounds Using a 6-Point TELER Scale on Day 14

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	p value Within treatment Baseline vs Day 14	Between-Treatment Comparison at Day 14 p value
Overall	1.0 (0.0, 1.0)	3.0 (1.0, 4.0)		0.0015
VT-1953 Topical Gel	0.5 (0.0, 1.0)	4.0 (3.0, 4.0)	0.0020	
Vehicle Topical Gel	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	>0.9999	

Between-treatment comparisons for Day 14 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 14) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Secondary outcome: Percentage of Patients Who Scored 3 to 5 on Malodor at Day 14 Using a QOL Component Scale

At Day 14, the proportion of patients with a malodour score of 4 in the VT-1953 Topical Gel treatment group was 70.0% (7 out of 10 patients), with a 95% confidence interval (CI) ranging from 41.6% to 98.4%. In contrast, no patients in the Vehicle Topical Gel group (0 out of 10) achieved a malodour score of 4, with a 95% CI of 0.0%. The difference in proportions between the VT-1953 Topical Gel and Vehicle Topical Gel groups was statistically significant, with a 95% CI for the difference ranging from 41.6% to 98.4% and a p-value of 0.0256.

Table 2: Percentage of Patients Who Scored 3 to 5 on Malodor At Day 14 Using a QOL Component Scale

Treatment Group	n(%)	95% CI for Proportion	95% CI for Proportion Difference	P Value
VT-1953 Topical Gel	7 (70.0%)	(41.6, 98.4)	(41.6, 98.4)	0.0256
Vehicle Topical Gel	0 (0.0%)	(0.0, 0.0)		

95% CIs for proportions and their differences are based on the normal approximation to the binomial distribution P-value calculated using Fisher's Exact Test between treatment groups

Secondary outcome: Score of Malodor Associated with Malignant Fungating Wounds Using a 6-point TELER Scale at Day 7

The secondary outcome assessing the score of malodor associated with malignant fungating wounds, as measured by investigators using a 6-point TELER Scale at Day 7, was evaluated. At baseline, the overall median malodor score was 1.0 (0.0, 1.0), which changed to a median of 1.0 (1.0, 2.0) at Day 7, with no statistically significant difference observed (p=0.1883). In the VT-1953 Topical Gel treatment group, the median malodor score improved from 0.5 (0.0, 1.0) at baseline to 1.5 (1.0, 3.0) at Day 7, which was statistically significant (p=0.0156). Conversely, the Vehicle Topical Gel group showed no change in median malodor score, remaining at 1.0 (1.0, 1.0) at both baseline and Day 7, with no significant difference (p>0.9999). The between-treatment comparison of malodor scores at Day 7 did not demonstrate a statistically significant difference (p=0.1883).

Table 3: Score of Malodor Associated with Malignant Fungating Wounds (scored by investigators) Using a 6-point TELER Scale at Day 7

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	p value Within treatment Baseline vs Day 7	Between-Treatment Comparison at Day 7 p value
Overall	1.0 (0.0, 1.0)	1.0 (1.0, 2.0)		0.1883
VT-1953 Topical Gel	0.5 (0.0, 1.0)	1.5 (1.0, 3.0)	0.0156	
Vehicle Topical Gel	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	>0.9999	

Between-treatment comparisons for Day 7 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 7) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Change in Score of Malodors Associated with Malignant Fungating Wounds Using a 6 point TELER Scale on Day 7 from Baseline

The change in malodor scores associated with malignant fungating wounds, as assessed by investigators using a 6-point TELER Scale, was evaluated on Day 7 from baseline. At baseline, the overall median score was 1.0 (0.0, 1.0), which remained at 1.0 (1.0, 2.0) on Day 7, resulting in a median change of 0.0 (0.0, 1.0). In the VT-1953 Topical Gel treatment group, the baseline median score was 0.5 (0.0, 1.0), which improved to 1.5 (1.0, 3.0) on Day 7, with a median change of 1.0 (0.0, 2.0). The Vehicle Topical Gel group had a baseline median score of 1.0 (1.0, 1.0), which remained unchanged at 1.0 (1.0, 1.0) on Day 7, with a median change of 0.0 (0.0, 0.0). The between-treatment comparison of the change from baseline to Day 7 demonstrated a statistically significant difference with a p value of 0.0157.

Table 4: Change in Score of Malodors Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale on Day 7 from Baseline

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	Change (Day 7-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 7-Baseline) p value
Overall	1.0 (0.0, 1.0)	1.0 (1.0, 2.0)	0.0 (0.0, 1.0)	0.0157
VT-1953 Topical Gel	0.5 (0.0, 1.0)	1.5 (1.0, 3.0)	1.0 (0.0, 2.0)	
Vehicle Topical Gel	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	0.0 (0.0, 0.0)	

Between-treatment comparisons for Change (Day 7-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Change in score of malodors associated with malignant fungating wounds using a 6 point TELER Scale on Day 14 from baseline

The change in malodor scores associated with malignant fungating wounds, as assessed by investigators using a 6-point TELER Scale, was evaluated on Day 14 from baseline. Overall, the median score improved from 1.0 (0.0, 1.0) at baseline to 3.0 (1.0, 4.0) on Day 14, with a median change of 2.0 (0.0, 4.0). In the VT-1953 Topical Gel treatment group, the median score improved from 0.5 (0.0, 1.0) at baseline to 4.0 (3.0, 4.0) on Day 14, resulting in a median change of 2.5 (2.0, 4.0). Conversely, the Vehicle Topical Gel group showed no change, with median scores remaining at 1.0 (1.0, 1.0) at both baseline and Day 14, and a median change of 0.0 (0.0, 0.0). The between-treatment comparison on the change from baseline to Day 14 demonstrated a statistically significant difference, with a p-value of 0.0021.

Table 5: Change in Score of Malodors Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale on Day 14 from Baseline

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	Change (Day 14-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 14-Baseline) p value
Overall	1.0 (0.0, 1.0)	3.0 (1.0, 4.0)	2.0 (0.0, 4.0)	0.0021
VT-1953 Topical Gel	0.5 (0.0, 1.0)	4.0 (3.0, 4.0)	2.5 (2.0, 4.0)	
Vehicle Topical Gel	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	0.0 (0.0, 0.0)	

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Between-treatment comparisons for Change (Day 14-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Percentage of Patients Who Score 4,5 on Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale at Day 7

In the VT-1953 Topical Gel treatment group, 1 patient (10.0%) had a score of 4, 5 on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER scale at day 7, with a 95% confidence interval (CI) for the proportion ranging from 0.0% to 28.6%. In contrast, no patients (0.0%) in the Vehicle Topical Gel group had a score of 4 or 5 on malodor, with a 95% CI of 0.0% to 0.0%. The 95% CI for the difference in proportions between the VT-1953 Topical Gel and Vehicle Topical Gel groups was 0.0% to 28.6%.

Table 6: Percentage of Patients Who Score 4,5 On Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale at Day 7

Treatment Group	n(%)	95% CI for Proportion	95% CI for Proportion Difference
VT-1953 Topical Gel	1 (10.0%)	(0.0, 28.6)	(0.0, 28.6)
Vehicle Topical Gel	0 (0.0%)	(0.0, 0.0)	

95% CIs for proportions and their differences are based on the normal approximation to the binomial distribution

Exploratory Outcome: Percentage of patients who score 4,5 on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at Day 14

The exploratory outcome data from the clinical trial indicated that 6 patients (60.0%) in the VT-1953 Topical Gel treatment group had a score of 4, 5 on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at day 14, with a 95% confidence interval (CI) for the proportion ranging from 29.6% to 90.4%. In contrast, no patients (0.0%) in the Vehicle Topical Gel group had the score of 4, 5, with a 95% CI of 0.0%. The 95% confidence interval for the difference in proportions between the VT-1953 Topical Gel and Vehicle Topical Gel groups was 29.6% to 90.4%, demonstrating a notable difference favoring the VT-1953 Topical Gel treatment.

Table 7: Percentage of Patients Who Score 4,5 on Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale at Day 14

Treatment Group	n(%)	95% CI for Proportion	95% CI for Proportion Difference
VT-1953 Topical Gel	6 (60.0%)	(29.6, 90.4)	(29.6, 90.4)
Vehicle Topical Gel	0 (0.0%)	(0.0, 0.0)	

95% CIs for proportions and their differences are based on the normal approximation to the binomial distribution

Exploratory Outcome: Percentage of Patients Who Exhibited ≥ 2-Point Improvement on Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale at Day 7

In the VT-1953 Topical Gel group, 3 patients (30.0%) exhibited ≥ 2-point improvement on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at Day 7, with a 95% confidence interval (CI) for the proportion ranging from 1.6% to 58.4%. In contrast, no patients (0.0%) in the Vehicle Topical Gel group exhibited ≥ 2-point improvement on malodor, with a 95% CI for the proportion of 0.0%. The 95% CI for the difference in proportions between the VT-1953 Topical Gel and Vehicle Topical Gel groups was 1.6% to 58.4%.

Table 8: Percentage of Patients Who Exhibited ≥ 2-Point Improvement on Malodor Associated With Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale at Day 7

Treatment Group	n(%)	95% CI for Proportion	95% CI for Proportion Difference
VT-1953 Topical Gel	3 (30.0%)	(1.6, 58.4)	(1.6, 58.4)
Vehicle Topical Gel	0 (0.0%)	(0.0, 0.0)	

95% CIs for proportions and their differences are based on the normal approximation to the binomial distribution

Exploratory Outcome: Percentage of Patients Who Exhibited ≥ 2-Point Improvement on Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 6-point TELER Scale at Day 14

In the VT-1953 Topical Gel treatment group, 8 patients (80.0%) exhibited ≥ 2-point improvement on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at Day 14, with a 95% confidence interval (CI) for the proportion ranging from 55.2% to 100.0%. In contrast, no patients (0.0%) in the Vehicle Topical Gel group exhibited ≥ 2-point improvement on malodor, with a 95% CI of 0.0% to 0.0%. The 95% CI for the difference in proportions between the VT-1953 Topical Gel and Vehicle Topical Gel groups was 55.2% to 100.0%, indicating a statistically significant difference favoring the VT-1953 Topical Gel.

Table 9: Percentage of patients who exhibited ≥ 2-point improvement on malodor associated with malignant fungating wounds (scored by investigators) using a 6-point TELER Scale at Day 14

Treatment Group	n(%)	95% CI for Proportion	95% CI for Proportion Difference
VT-1953 Topical Gel	8 (80.0%)	(55.2, 100.0)	(55.2, 100.0)
Vehicle Topical Gel	0 (0.0%)	(0.0, 0.0)	

95% CIs for proportions and their differences are based on the normal approximation to the binomial distribution

Exploratory Outcome: Score Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 10-point VAS Scale at Day 7

The malodor associated with malignant fungating wounds was assessed using a 10-point Visual Analog Scale (VAS) by investigators at baseline and Day 7. At baseline, the overall median malodor score was 7.0 (6.0, 8.0), which decreased to 6.0 (5.0, 7.0) at Day 7. In the VT-1953 Topical Gel treatment group, the median malodor score decreased from 7.5 (7.0, 9.0) at baseline to 5.5 (5.0, 6.0) at Day 7, showing a statistically significant reduction (p = 0.0020). Conversely, in the Vehicle Topical Gel group, the median malodor score increased from 6.0 (5.0, 6.0) at baseline to 7.0 (6.0, 7.0) at Day 7, which was not statistically significant (p = 0.0625). The between-treatment comparison at day 7 between the 2 groups was statistically significant (p=0.0499).

Table 10: Score Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using A 10-point VAS Scale at Day 7

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	p value Within treatment Baseline vs Day 7	Between-Treatment Comparison at Day 7 p value
Overall	7.0 (6.0, 8.0)	6.0 (5.0, 7.0)		0.0499
VT-1953 Topical Gel	7.5 (7.0, 9.0)	5.5 (5.0, 6.0)	0.0020	
Vehicle Topical Gel	6.0 (5.0, 6.0)	7.0 (6.0, 7.0)	0.0625	

Between-treatment comparisons for Day 7 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 7) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Score Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 10-point VAS Scale at Day 14

Overall, the median malodor score decreased from 7.0 (6.0, 8.0) at baseline to 3.0 (2.0, 6.0) at Day 14. In the VT-1953 Topical Gel treatment group, the median score reduced from 7.5 (7.0, 9.0) at baseline to 2.5 (2.0, 3.0) at Day 14, showing a significant improvement (p=0.0020). Conversely, the Vehicle Topical Gel group showed an increase in median malodor score from 6.0 (5.0, 6.0) at baseline to 7.0 (6.0, 7.0) at Day 14, which was not statistically significant (p=0.0625). The between-treatment comparison at day 14 between the VT-1953 topical gel and vehicle topical gel was statistically significant (p=0.0023).

Table 11: Score Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 10-point VAS Scale at Day 14

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	p value Within treatment Baseline vs Day 14	Between-Treatment Comparison at Day 14 p value
Overall	7.0 (6.0, 8.0)	3.0 (2.0, 6.0)		0.0023
VT-1953 Topical Gel	7.5 (7.0, 9.0)	2.5 (2.0, 3.0)	0.0020	
Vehicle Topical Gel	6.0 (5.0, 6.0)	7.0 (6.0, 7.0)	0.0625	

Between-treatment comparisons for Day 14 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 14) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Change in Score Of Malodor Associated with Malignant Fungating Wounds (Scored byInvestigators) Using a 10-point VAS Scale at Day 7

At baseline, the overall median malodor score was 7.0 (6.0, 8.0). By Day 7, the overall median score decreased to 6.0 (5.0, 7.0), with a median change from baseline of -1.0 (-3.0, 1.0). This change was statistically significant with a between-treatment comparison p value of 0.0017. In the VT-1953 Topical Gel group, the baseline median score was 7.5 (7.0, 9.0), which decreased (improved) to 5.5 (5.0, 6.0) at Day 7, resulting in a median change of -2.5 (-3.0, -1.0) which was statistically significant. Conversely, the Vehicle Topical Gel group had a baseline median score of 6.0 (5.0, 6.0), which increased (worsened) to 7.0 (6.0, 7.0) at Day 7, with a median change of 1.0 (1.0, 1.0). The between-treatment comparison on change from baseline to day 7 was statistical significant (p=0.0017), indicating a reduction in malodor scores with VT-1953 Topical Gel treatment compared the vehicle gel.

Table 12: Change in Score of Malodor Associated with Malignant Fungating Wounds (Scored by Patients) Using A 10-point VAS Scale at Day 7

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	Change (Day 7-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 7-Baseline) p value
Overall	7.0 (6.0, 8.0)	6.0 (5.0, 7.0)	-1.0 (-3.0, 1.0)	0.0017
VT-1953 Topical Gel	7.5 (7.0, 9.0)	5.5 (5.0, 6.0)	-2.5 (-3.0, -1.0)	
Vehicle Topical Gel	6.0 (5.0, 6.0)	7.0 (6.0, 7.0)	1.0 (1.0, 1.0)	

Between-treatment comparisons for Change (Day 7-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Change in Score of Malodor Associated with Malignant Fungating Wounds (Scored by Investigators) Using a 10-point VAS Scale at Day 14

The analysis of change in Malodor Visual Analog Scale (VAS) scores from baseline to Day 14 demonstrated an improvement in the overall treatment group, with a median change of -4.0 (-6.0, 1.0). Specifically, the VT-1953 Topical Gel group showed a median baseline VAS score of 7.5 (7.0, 9.0) which decreased (improved) to 2.5 (2.0, 3.0) at Day 14, resulting in a median change of -5.0 (-6.0, -4.0). In contrast, the Vehicle Topical Gel group had a median baseline score of 6.0 (5.0, 6.0) which increased (worsened) to 7.0 (6.0, 7.0) at Day 14, with a median change of 1.0 (1.0, 1.0). The between-treatment comparison on change from the baseline to day 14 was statistically significant indicating a significant reduction in malodor severity with VT-1953 Topical Gel compared to the vehicle.

Table 13: Change in Score of Malodor Associated with Malignant Fungating Wounds (Scored by patients) Using a 10-point VAS Scale at Day 14

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	Change (Day 14-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 14-Baseline) p value
Overall	7.0 (6.0, 8.0)	3.0 (2.0, 6.0)	-4.0 (-6.0, 1.0)	0.0021
VT-1953 Topical Gel	7.5 (7.0, 9.0)	2.5 (2.0, 3.0)	-5.0 (-6.0, -4.0)	
Vehicle Topical Gel	6.0 (5.0, 6.0)	7.0 (6.0, 7.0)	1.0 (1.0, 1.0)	

Between-treatment comparisons for Change (Day 14-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Pain Score Associated with the Wound as Scored by the Patient Using a 10-point Visual Analog Scale on Day 7

The exploratory outcome assessing pain associated with the wound was measured using a 10-point Visual Analog Scale (VAS) at baseline and on Day 7. Overall, the median pain score decreased from 6.0 (5.0, 7.0) at baseline to 5.0 (4.0, 6.0) on Day 7. In the VT-1953 Topical Gel treatment group, the median pain score significantly decreased from 6.0 (5.0, 7.0) at baseline to 4.5 (4.0, 6.0) on Day 7, with a p-value of 0.0020, demonstrating a statistically significant reduction in pain. Conversely, in the Vehicle Topical Gel group, the median pain score remained unchanged at 6.0 (6.0, 6.0) from baseline to Day 7, with a p-value greater than 0.9999, indicating no change in pain levels. Between-treatment comparison at day 7 was not statistically significant (p=0.0766).

Table 14: Pain Score Associated with the Wound as Scored by the Patient Using a 10-point Visual Analog Scale on Day 7

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	p value Within treatment Baseline vs Day 7	Between-Treatment Comparison at Day 7 p value
Overall	6.0 (5.0, 7.0)	5.0 (4.0, 6.0)		0.0766
VT-1953 Topical Gel	6.0 (5.0, 7.0)	4.5 (4.0, 6.0)	0.0020	
Vehicle Topical Gel	6.0 (6.0, 6.0)	6.0 (6.0, 6.0)	>0.9999	

Between-treatment comparisons for Day 7 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 7) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Pain Score Associated with the Wound as Scored by the Patient Using a 10-point Visual Analog Scale on Day 14

The exploratory outcome assessing pain associated with the wound was measured using a 10-point Visual Analog Scale (VAS) on Day 14. At baseline, the overall median pain score was 6.0 (5.0, 7.0). By Day 14, the overall median pain score decreased to 4.0 (3.0, 6.0), demonstrating a statistically significant reduction ($p = 0.0026$). In the VT-1953 Topical Gel treatment group, the median pain score at baseline was 6.0 (5.0, 7.0), which decreased significantly to 4.0 (3.0, 4.0) on Day 14 ($p = 0.0020$). Conversely, the Vehicle Topical Gel group showed no change in median pain score, remaining at 6.0 (6.0, 6.0) from baseline to Day 14, with no statistically significant difference observed ($p > 0.9999$). Between-treatment comparison at Day 14 between the 2 groups was statistically significant (p=0.0026) indicating that VT-1953 topical gel was superior to Vehicle topical gel in reducing pain.

Table 15: Pain Score Associated with the Wound as Scored by the Patient Using a 10-point Visual Analog Scale on Day 14

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	p value Within treatment Baseline vs Day 14	Between-Treatment Comparison at Day 14 p value
Overall	6.0 (5.0, 7.0)	4.0 (3.0, 6.0)		0.0026
VT-1953 Topical Gel	6.0 (5.0, 7.0)	4.0 (3.0, 4.0)	0.0020	
Vehicle Topical Gel	6.0 (6.0, 6.0)	6.0 (6.0, 6.0)	>0.9999	

Between-treatment comparisons for Day 14 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 14) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Change in Pain Score Associated with the Wound as Scored by the Patient Using a 10-Point Visual Analog Scale on Day 7

The exploratory outcome assessing the change in pain score associated with the wound, as measured by the patient using a 10-point Visual Analog Scale on Day 7, demonstrated a reduction in pain in the overall population. The median pain score decreased from 6.0 (5.0, 7.0) at baseline to 5.0 (4.0, 6.0) on Day 7, with a median change of 1.0 (0.0, 2.0. In the VT-1953 Topical Gel treatment group, the median pain score decreased from 6.0 (5.0, 7.0) at baseline to 4.5 (4.0, 6.0) on Day 7, with a median change of 1.5 (1.0, 2.0). In contrast, the Vehicle Topical Gel group showed no change in median pain score, remaining at 6.0 (6.0, 6.0) at both baseline and Day 7, with a median change of 0.0 (0.0, 0.0). The between-treatment comparison on change from baseline to day 7 was statistical significant (p=0.0045) indicating that treatment with VT-1953 Topical Gel was associated with a greater reduction in wound-associated pain compared to the vehicle.

Table 16: Change in Pain Score Associated with the Wound as Scored by the Patient Using a 10-point Visual Analog Scale on Day

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	Change (Day 7-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 7-Baseline) p value
Overall	6.0 (5.0, 7.0)	5.0 (4.0, 6.0)	1.0 (0.0, 2.0)	0.0045
VT-1953 Topical Gel	6.0 (5.0, 7.0)	4.5 (4.0, 6.0)	1.5 (1.0, 2.0)	
Vehicle Topical Gel	6.0 (6.0, 6.0)	6.0 (6.0, 6.0)	0.0 (0.0, 0.0)	

Between-treatment comparisons for Change (Day 7-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Change in pain score associated with the wound as scored by the patient using a 10-point Visual Analog Scale on Day 14

The change in pain score associated with the wound, as assessed by patients using a 10-point Visual Analog Scale (VAS) on Day 14, was evaluated. At baseline, the overall median pain score was 6.0 (5.0, 7.0). By Day 14, the overall median pain score decreased to 4.0 (3.0, 6.0), resulting in a median change from baseline of 2.0 (0.0, 4.0). In the VT-1953 Topical Gel treatment group, the median baseline pain score was 6.0 (5.0, 7.0), which decreased to 4.0 (3.0, 4.0) on Day 14. The median change from baseline in this group was 3.0 (2.0, 4.0). In contrast, the Vehicle Topical Gel group had a median baseline pain score of 6.0 (6.0, 6.0) that remained unchanged at 6.0 (6.0, 6.0) on Day 14, with a median change of 0.0 (0.0, 0.0). The between-treatment comparison on change from baseline to day 14 was statistically significant (p=0.0028) indicating a greater reduction in pain scores in the VT-1953 Topical Gel group compared to the Vehicle Topical Gel group by Day 14.

Table 17: Change in Pain Score Associated with the Wound as Scored by the Patient Using a 10-point Visual Analog Scale on Day 14

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	Change (Day 14-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 14-Baseline) p value
Overall	6.0 (5.0, 7.0)	4.0 (3.0, 6.0)	2.0 (0.0, 4.0)	0.0028
VT-1953 Topical Gel	6.0 (5.0, 7.0)	4.0 (3.0, 4.0)	3.0 (2.0, 4.0)	
Vehicle Topical Gel	6.0 (6.0, 6.0)	6.0 (6.0, 6.0)	0.0 (0.0, 0.0)	

Between-treatment comparisons for Change (Day 14-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Score of Exudates as Scored by the Caregiver Measured on 0-4 Scale on Day 7

For the overall population, the median value of the score of exudates as scored by the caregiver measured on 0-4 scale on day 7, remained stable at 4.0 (3.0, 5.0) from baseline to Day 7. In the VT-1953 Topical Gel treatment group, the median value decreased slightly from 4.0 (3.0, 4.0) at baseline to 3.5 (3.0, 4.0) at Day 7; however, this change was not statistically significant (p=0.5000). The Vehicle Topical Gel group showed no change in median values, remaining at 5.0 (4.0, 5.0) at both baseline and Day 7, with no p value reported for within-group comparison. Between-treatment comparison at Day 7 between the 2 groups was statistically significant (p=0.0268).

Table 18: Score of Exudates as Scored by the Caregiver Measured on 0-4 Scale on Day 7

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	p value Within treatment Baseline vs Day 7	Between-Treatment Comparison at Day 7 p value
Overall	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)		0.0268
VT-1953 Topical Gel	4.0 (3.0, 4.0)	3.5 (3.0, 4.0)	0.5000	
Vehicle Topical Gel	5.0 (4.0, 5.0)	5.0 (4.0, 5.0)	-	

Between-treatment comparisons for Day 7 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 7) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Score of Exudates as Scored by the Caregiver Measured on 0-4 Scale on Day 14

Overall, the median exudate score at baseline was 4.0 (3.0, 5.0) and remained unchanged at Day 14 with a median of 4.0 (3.0, 5.0). In the VT-1953 Topical Gel treatment group, the median exudate score decreased from 4.0 (3.0, 4.0) at baseline to 3.5 (3.0, 4.0) at Day 14; however, this change was not statistically significant (p = 0.5000). In the Vehicle Topical Gel group, the median exudate score remained stable at 5.0 (4.0, 5.0) from baseline through Day 14, with no p value reported for within-group comparison. Between-treatment comparison at Day 14 was statistically significant (p=0.0268).

Table 19: Score of Exudates as Scored by the Caregiver Measured on 0-4 Scale on Day 14

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	p value Within treatment Baseline vs Day 14	Between-Treatment Comparison at Day 14 p value
Overall	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)		0.0268
VT-1953 Topical Gel	4.0 (3.0, 4.0)	3.5 (3.0, 4.0)	0.5000	
Vehicle Topical Gel	5.0 (4.0, 5.0)	5.0 (4.0, 5.0)	-	

Between-treatment comparisons for Day 7 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 7) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Quality of Life (QOL) Score on VAS Scale at Day 7 as Scored by the Patient

At baseline, the overall median QoL score was 5.0 (4.5, 5.8), which decreased to 4.5 (3.8, 5.0) at Day 7. In the VT-1953 Topical Gel treatment group, the median QoL score significantly decreased (i.e. improvement in QoL) from 5.5 (4.5, 6.0) at baseline to 4.1 (3.5, 4.8) at Day 7 (p = 0.0020). Conversely, the Vehicle Topical Gel group showed a non-significant increase in median QoL score (worsening of QoL) from 4.8 (4.3, 4.8) at baseline to 5.0 (4.5, 5.0) at Day 7 (p = 0.0625). No statistically significant difference was observed between the treatment groups at Day 7 (p=0.0937).

Table 20: Quality of Life (QOL) Score on VAS Scale at Day 7 as Scored by the Patient

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	p value Within treatment Baseline vs Day 7	Between-Treatment Comparison at Day 7 p value
Overall	5.0 (4.5, 5.8)	4.5 (3.8, 5.0)		0.0937
VT-1953 Topical Gel	5.5 (4.5, 6.0)	4.1 (3.5, 4.8)	0.0020	
Vehicle Topical Gel	4.8 (4.3, 4.8)	5.0 (4.5, 5.0)	0.0625	

Between-treatment comparisons for Day 7 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 7) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Quality of Life (QOL) Score on VAS Scale at Day 14 as Scored by the Patient

In the VT-1953 Topical Gel treatment group, the median QoL score decreased from 5.5 (4.5, 6.0) at baseline to 3.0 (2.8, 3.3) at Day 14, showing a statistically significant improvement in QoL (p = 0.0020). Conversely, the Vehicle Topical Gel group showed a median QoL score of 4.8 (4.3, 4.8) at baseline and 5.0 (4.5, 5.0) at Day 14, with no statistically significant change observed (p = 0.0625). Between-treatment comparison at Day 14 between the 2 groups was statistically significant (p=0.0032).

Table 21: Quality of Life (QOL) Score on VAS Scale at Day 14 as Scored by the Patient

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	p value Within treatment Baseline vs Day 14	Between-Treatment Comparison at Day 14 p value
Overall	5.0 (4.5, 5.8)	3.3 (2.8, 4.5)		0.0032
VT-1953 Topical Gel	5.5 (4.5, 6.0)	3.0 (2.8, 3.3)	0.0020	
Vehicle Topical Gel	4.8 (4.3, 4.8)	5.0 (4.5, 5.0)	0.0625	

Between-treatment comparisons for Day 14 scores were performed using the Wilcoxon Rank-Sum Test.

Within-treatment comparisons (Baseline versus Day 14) for each treatment group were performed using the Wilcoxon Signed-Rank Test.

Exploratory Outcome: Change in Quality of Life (QOL) score on VAS scale at Day 7 as scored by the patient

In the VT-1953 Topical Gel treatment group, the median QoL score decreased (i.e. improvement in QoL) from 5.5 (4.5, 6.0) at Baseline to 4.1 (3.5, 4.8) at Day 7, with a median change of 1.3 (1.0, 1.5). In contrast, the Vehicle Topical Gel group showed a slight increase in median QoL score from 4.8 (4.3, 4.8) at Baseline to 5.0 (4.5, 5.0) at Day 7, with a median change of 0.3 (0.3, 0.3), i.e. worsening of QoL. The between-treatment comparison on the change from Baseline to Day 7 demonstrated a statistically significant difference favoring the VT-1953 Topical Gel group (p = 0.0021).

Table 22: Statistical Summary of Change QoL Scored by patient from Baseline to Day 7

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	Change (Day 7-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 7-Baseline) p value
Overall	5.0 (4.5, 5.8)	4.5 (3.8, 5.0)	1.0 (0.3, 1.3)	0.0021
VT-1953 Topical Gel	5.5 (4.5, 6.0)	4.1 (3.5, 4.8)	1.3 (1.0, 1.5)	
Vehicle Topical Gel	4.8 (4.3, 4.8)	5.0 (4.5, 5.0)	0.3 (0.3, 0.3)	

Between-treatment comparisons for Change (Day 7-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Change in quality of Life (QOL) score on VAS scale at Day 14 as scored by the patient

In the VT-1953 Topical Gel treatment group, the median QOL score improved from 5.5 (4.5, 6.0) at baseline to 3.0 (2.8, 3.3) at Day 14, with a median change of 2.4 (2.0, 3.0), i.e. an improvement in QoL. Conversely, the Vehicle Topical Gel group showed minimal change, with median scores of 4.8 (4.3, 4.8) at baseline and 5.0 (4.5, 5.0) at Day 14, resulting in a median change of 0.3 (0.3, 0.3). The between-treatment comparison on change from baseline to day 7 was not statistical significant (p=0.0024). These results indicate a greater improvement in QOL scores in the VT-1953 Topical Gel group compared to the vehicle control.

Table 23: Change in Quality of Life (QOL) Score on VAS Scale at Day 14 as Scored by the Patient

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	Change (Day 14-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 14-Baseline) p value
Overall	5.0 (4.5, 5.8)	3.3 (2.8, 4.5)	2.0 (0.3, 2.5)	0.0024
VT-1953 Topical Gel	5.5 (4.5, 6.0)	3.0 (2.8, 3.3)	2.4 (2.0, 3.0)	
Vehicle Topical Gel	4.8 (4.3, 4.8)	5.0 (4.5, 5.0)	0.3 (0.3, 0.3)	

Between-treatment comparisons for Change (Day 14-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Statistical Summary of Change from Baseline to Day 7 in Exudate Amount on the 5 Point Scale

The exploratory outcome assessing the change from baseline to Day 7 in exudate amount, measured on a 5-point scale, was summarized for both treatment groups. At baseline, the overall median exudate score was 4.0 (3.0, 5.0), which remained unchanged at Day 7 with a median of 4.0 (3.0, 5.0). The median change from baseline to Day 7 was 0.0 (0.0, 0.0) overall, indicating no median change in exudate amount. In the VT-1953 Topical Gel group, the baseline median was 4.0 (3.0, 4.0), which decreased slightly to 3.5 (3.0, 4.0) at Day 7; however, the median change remained 0.0 (0.0, 0.0). In the Vehicle Topical Gel group, the baseline and Day 7 medians were both 5.0 (4.0, 5.0), with a median change of 0.0 (0.0, 0.0). The between-treatment comparison of the change from baseline to Day 7 in exudate amount yielded a p-value of 0.3503, indicating no statistically significant difference between the VT-1953 Topical Gel and Vehicle Topical Gel groups.

Table 24: Statistical Summary of Change from Baseline to Day 7 in Exudate Amount on a 5 Point Scale

Treatment Group	Baseline Median (Q1, Q3)	Day 7 Median (Q1, Q3)	Change (Day 7 - Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 7-Baseline) p value
Overall	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	0.0 (0.0, 0.0)	0.3503
VT-1953 Topical Gel	4.0 (3.0, 4.0)	3.5 (3.0, 4.0)	0.0 (0.0, 0.0)	
Vehicle Topical Gel	5.0 (4.0, 5.0)	5.0 (4.0, 5.0)	0.0 (0.0, 0.0)	

Between-treatment comparisons for Change (Day 7-Baseline) were performed using the Wilcoxon Rank-Sum Test.

Exploratory Outcome: Statistical Summary of Change from Baseline to Day 14 in Exudate Amount on the 5 Point Scale (Annexure no 10)

The exploratory outcome assessing the change from baseline to Day 14 in exudate amount, measured on a 5-point scale, was summarized for both treatment groups. At baseline, the median exudate score for the overall population was 4.0 (3.0, 5.0), which remained unchanged at Day 14 with a median of 4.0 (3.0, 5.0). The median change from baseline to Day 14 was 0.0 (0.0, 0.0) for the overall population. Specifically, the VT-1953 Topical Gel group had a baseline median exudate score of 4.0 (3.0, 4.0) and a Day 14 median of 3.5 (3.0, 4.0), resulting in a median change of 0.0 (0.0, 0.0). The Vehicle Topical Gel group had a baseline median of 5.0 (4.0, 5.0) and a Day 14 median of 5.0 (4.0, 5.0), with a median change of 0.0 (0.0, 0.0). The between-treatment comparison on change from baseline to day 14 was not statistical significant (p=0.3503). These results indicated no meaningful change in exudate amount over the 14-day treatment period in either group.

Table 25: Statistical Summary of Change from Baseline to Day 14 in Exudate Amount on a 5 Point Scale

Treatment Group	Baseline Median (Q1, Q3)	Day 14 Median (Q1, Q3)	Change (Day 14-Baseline) Median (Q1, Q3)	Between-Treatment Comparison on Change (Day 14-Baseline) p value
Overall	4.0 (3.0, 5.0)	4.0 (3.0, 5.0)	0.0 (0.0, 0.0)	0.3503
VT-1953 Topical Gel	4.0 (3.0, 4.0)	3.5 (3.0, 4.0)	0.0 (0.0, 0.0)	
Vehicle Topical Gel	5.0 (4.0, 5.0)	5.0 (4.0, 5.0)	0.0 (0.0, 0.0)	

Between-treatment comparisons for Change (Day 14-Baseline) were performed using the Wilcoxon Rank-Sum Test.

In summary:

VT-1953 significantly reduces the malodor symptom of MFW, consistent with its mechanism of action. A large fraction of the patients reported an improvement in maolodor symptoms with VT-1953 as compared to vehicle treatment. Of all wound related symptoms, malodor is cited by patients and professionals as the most distressing, contributing to social isolation, depression, feelings of guilt and repulsion (Gethin, G., et al. Current practice in the management of wound odour: An international survey. *International Journal of Nursing Studies* 2014; **51**, 865-874, https://doi.org/10.1016/j.ijnurstu.2013.10.013). In a survey of nurses, 48% identified malodor as the main challenge, followed by pain and exudate control (Probst, S.et al. Malignant fungating wounds: a survey of nurses' clinical practice in Switzerland. *Eur J Oncol Nurs* 2009; **13**, 295-298, doi:10.1016/j.ejon.2009.03.008). Patients report feelings of being totally isolated, attributing the malodor as the main causative factor (Gethin, 2014). The feelings of isolation also result in patients and care givers struggling in their attempts to manage the physical aspects of the wound while simultaneously coping with the psychological impact of its appearance as a constant reminder of underlying malignancy (Gethin, 2014).

Malodor in MFW arises from bacterial colonization (Fromantin I., et al. Bacterial floras and biofilms of malignant wounds associated with breast cancers. J. Clin. Microbiol. 2013; 51, 3368–3373). VT-1953 inhibits DNA Gyr and Topoisomerase 4, and therefore 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 even though it only kills anaerobic bacteria.

VT-1953 also reduced pain symptoms associated with the lesion. Fromantin et al had reported that pain correlates with the bacterial load. Inflammation can also contribute to pain. VT-1953 not only kills bacteria but can contribute to reducing inflammation-associated symptoms by inhibiting MD2-TLR signaling. Multiple clinical trials have demonstrated the reduction of inflammation following VT-1953 topical gel application. VT-1953 did not impact exudate, consistent with the mechanism of action not overlapping with the pathology (cancer) driving exudate.

The 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 malodor associated with malodorous MFW. The results from the Ph2 will inform our Ph3 design (We have not had any meetings with the FDA regarding Phase 3 trial protocols). To date, we have submitted an application to the USFDA for an 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. Destum Partners, Inc, an independent life sciences advisory firm, conducted a commercial opportunity assessment for VT-1953 for the treatment of malignant fungating wounds (MFW), a severe complication associated with advanced cancers characterized by malodor, pain, and significant quality-of-life impact. The assessment incorporated epidemiology modeling, primary research with oncology and wound care key opinion leaders (KOLs), review of treatment patterns, competitive landscape analysis, and pricing benchmarks. Based on this analysis, Destum Partners estimated approximately 58,000 new MFW cases annually in the United States and identified a significant unmet medical need due to the absence of FDA-approved pharmacologic therapies specifically indicated for this condition. Destum Partners estimated the potential annual addressable U.S. market opportunity for pharmacologic treatment of MFW at approximately $2.2 billion. Using a commercial forecast model and risk-adjusted net present value methodology, Destum Partners projected potential peak annual U.S. net sales for VT-1953 of approximately $600 million, assuming successful clinical development and commercialization. Based on available Phase 2 clinical data and development assumptions at the time of the analysis, the report estimated a risk-adjusted asset value of approximately $455 million, which Destum Partners indicated could increase to approximately $1 billion upon successful completion of Phase 3 clinical development and regulatory approval

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

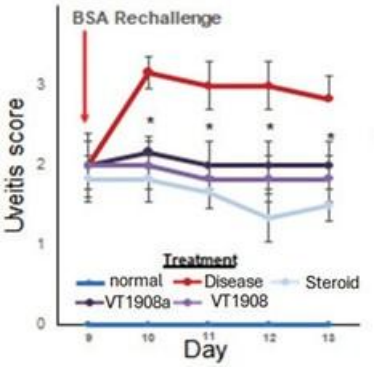
Topical steroids are the first line of treatment for non-infectious uveitis. Steroids deplete the immune cells attacking the uvea. However, long-term use of steroids, such as in chronic and recurrent uveitis, can lead to complications, including glaucoma and cataract. Additionally, uveitic glaucoma is 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.

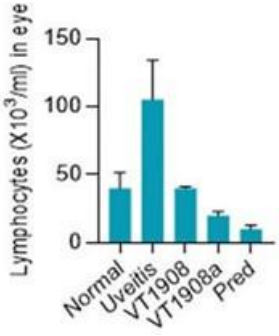
In preclinical studies, treatment with mycophenolate topical eye drops resulted in significant resolution of uveitis comparable to steroid treatment, and reduced the number of infiltrating immune cells in the eye (See Figure11). Mycophenolate is already approved by the FDA as an oral treatment of transplant 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.

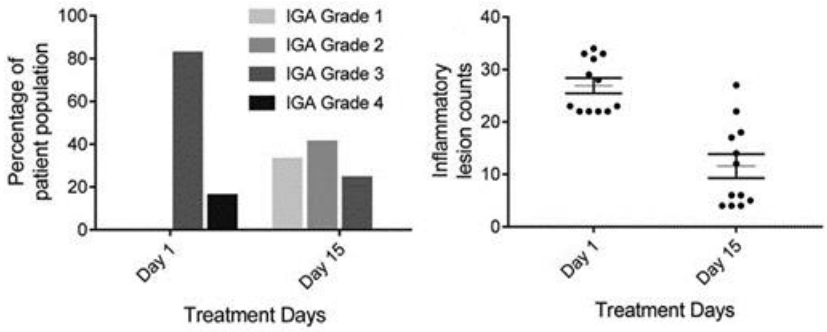
Other pipeline opportunities

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 the 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 descriptions, 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 **Figure 12**).

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.



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.

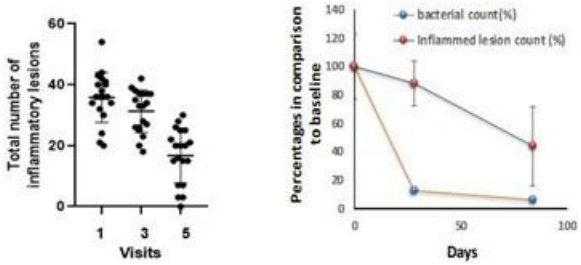
No occurrence of treatment-emergent AEs (TEAEs; local or systemic) or changes in vital signs, physical examinations and urinalysis were reported for any patients during the course of the entire study. A negligible number of LSRs (erythema, edema, scaling, stinging/burning, and pruritus/itching) were 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.

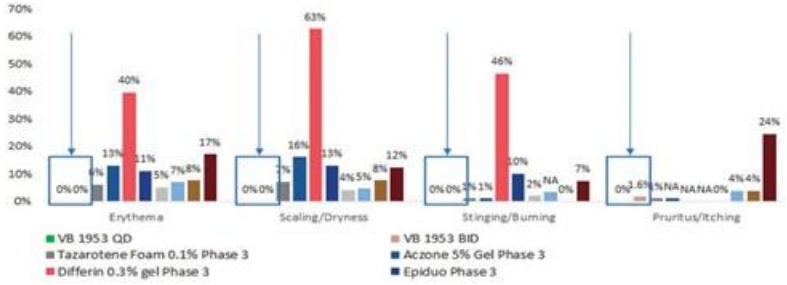
The clinical investigator concluded, 'VB-1953 showcased good efficacy in treating both inflammatory and noninflammatory acne lesions without serious adverse effects. While larger studies are necessary to confirm these findings, our present data suggest VB-1953 as a future therapy against acne, even with 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.



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).

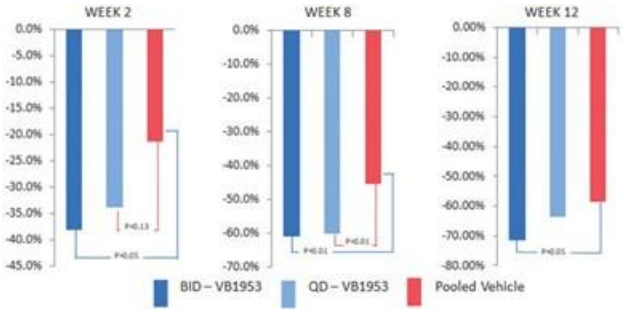
Figure 14. VB-1953 topical gel was well tolerated in a Ph 2 study safety analysis. Percentage of subjects with Local Skin Reaction (LSR)-Moderate and above grade of the LSR at Week 12



* Comparative data was collected from published sources. Trial did not involve direct comparison.

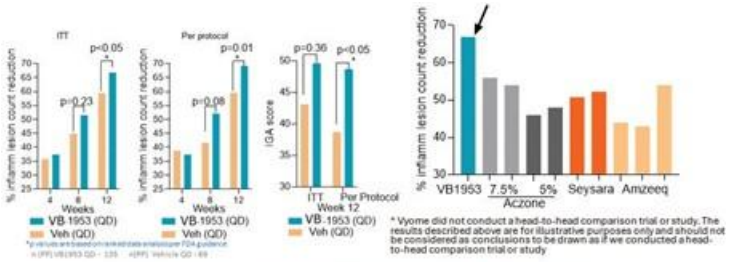
In 106 evaluable patients across the treatment groups, VB-1953 significantly reduced inflammatory lesions with an early onset of action. At two weeks of treatment, VB-1953, applied twice daily (b.i.d) reduced inflammatory lesions by >35% (20% for placebo). At 12 weeks of treatment, VB-1953 (b.i.d) reduced inflammatory lesions by over 70% (See **Figure 15**).

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 **Figure 16**). 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

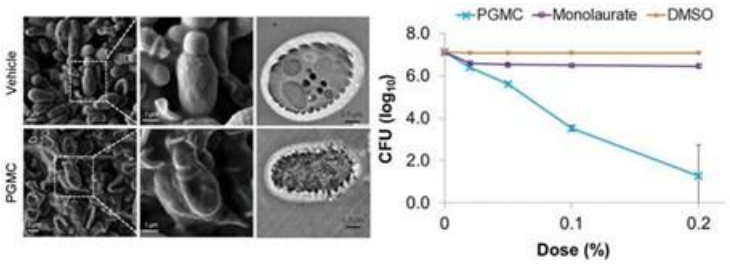
Market opportunity for VB-1953

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. This license was terminated in December 2024.

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 Our 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.

VT 1953: A method of treating Malignant fungating wound using Besifloxacin.				
Country	**Patent Application Number/ Granted Patent Number**	**Current Status**	**Expiry Period**	**Type of Protection**
PCT	Patent Application Number: PCT/US25/33442	National phase application filling due by December 2026.	June 2044	Formulation and use
VT 1908: Formulations and Method for Treatment of Inflammatory Diseases.				
Country	**Patent Application Number/ Granted Patent Number**	**Current Status**	**Expiry Period**	**Type of 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
MRT Technology based products				
Country	**Patent Application Number/ Granted Patent Number**	**Current Status**	**Expiry Period**	**Type of 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

VB 1953: Treatment of Resistant Acne				
Country	**Patent Application Number/ Granted Patent Number**	**Current Status**	**Expiry Period**	**Type of 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
Hong 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
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

Miscellaneous Patent Applications				
Country	**Patent Application Number/ Granted Patent Number**	**Current Status**	**Expiry Period**	**Type of Protection**
Japan	Granted Patent Number: JP6336902B2	Granted Patent	December 2033	Composition of matter, Formulation and use
USA	Granted Patent Number: US9907812B2	Granted Patent	December 2033	Composition of matter, Formulation and use
Hong Kong	Patent Application Number: 16108710.4	Application under examination	July 2036	Formulation and use
India	Patent Application Number: 6759/CHENP/2015	Application under examination	July 2036	Formulation and use
China	Patent Application Number: 201680054112.2	Application under examination	February 2038	Composition of matter, Formulation and use
India	Granted Patent Number: 466679	Granted Patent	February 2038	Composition of matter, Formulation and use
South Korea	Granted Patent Number: 10-2123365	Granted Patent	February 2038	Composition of matter, Formulation and use
USA	Granted Patent Number: US10570152B2	Granted Patent	February 2038	Composition of matter, 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 Our 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 entered into a Development and Licensing Agreement with Sun Pharma, under which 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 $59,000), 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 $118,000). 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 $118,000) upon a positive or satisfactory of the clinical trial study conducted on the product. Since the clinical trial study was not initiated and completed in defined timeline by Sun Pharma, the clinical trial was deemed to be completed with a positive outcome and a payment in the amount of INR 10,000,000 (approximately $118,000) was received in April 2025. 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 $118,000) (upon net sales of all products of INR 250,000,000 (approximately $2,965,000) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(b) INR 15,000,000 (approximately $178,000) (upon net sales of all products of INR 500,000,000 (approximately $5,931,000) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(c) INR 10,000,000 (approximately $118,000) (upon net sales of all products of INR 750,000,000 (approximately $8,896,000) in any consecutive 12 months or any 12 months in any consecutive 24 months whichever is earlier),

(d) INR 10,000,000 (approximately $118,000) (for every INR 250,000,000 (approximately $2,956,000) incremental sales of all products together upon net sales of INR 1,000,000,000 (approximately $11,862,000) 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 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 December 31, 2025, we had 18 employees/retainers, of which 9 were full-time and 9 were part-time. All of 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 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.

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. On August 14, 2025, we completed a merger with ReShape Lifesciences Inc. Our principal executive offices are located at Harvard Square, One Mifflin Place, Suite 400, Cambridge, MA 02138. Our 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 Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

Our common stock is quoted on the Nasdaq under the symbol "HIND". We file annual, quarterly, and current reports, proxy statements and other information with the U.S. Securities Exchange Commission (the "SEC") and are subject to the requirements of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). These filings are available to the public on the Internet at the SEC's website at *http://www.sec.gov*.

ITEM 1A. RISK FACTORS

SUMMARY OF 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 Our Limited Operating History, Financial Condition and Capital Requirements

- We have a limited operating history and have not taken a product through to commercialization.
- 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.
- Our ability to use net operating losses ("NOL") carryforwards may be limited.
- Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.
- 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.
- 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.
- 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 may in the future license additional assets, which may require us to expend additional resources and raise additional capital.
- We may not realize all of the anticipated benefits of the Merger.
- We have incurred substantial direct and indirect costs as a result of the Merger and expect to incur substantial direct and indirect costs following the Merger.
- If the perceived benefits of the Merger do not meet the expectations of investors or securities analysts, the market price of our securities may decline.
- Our operating results may fluctuate significantly.
- If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of its common stock.
- Certain of our directors and executive officers also work with other companies and organizations and such other positions may create conflicts of interest in the future.

Risks Related to Our 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 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.

Risks Related to Our 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 have 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.
- Public health crises such as pandemics or similar outbreaks have affected and could continue to seriously and adversely affect our preclinical studies and anticipated clinical trials, business, financial condition and results of operations.
- Our business, operations, financial position and clinical development plans and timelines could be materially adversely affected by the ongoing conflicts in various parts of the world.

Risks Related to Our 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.

- 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.

- 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.

- 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.

- We generates all of our revenues from one customer, and loss of business from such customer could significantly harm our revenues and business.

- 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 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 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.

- The increasing use of social media platforms presents new risks and challenges.

- Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

- If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired, which may adversely affect investor confidence in us and, as a result, the market price of our common stock.

- 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.

Risks Related to Our Intellectual Property

- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

- 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.

- 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.

- Issued patents covering one or more of our drug candidates could be found invalid or unenforceable.

- 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.

- Patent terms may be inadequate to protect our competitive position with respect to the Vyome Assets for an adequate amount of time.
- 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.
- 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.
- 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 may be subject to claims challenging the inventorship of our patents and other intellectual property.
- 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.
- We may not be able to effectively secure first-tier technologies when competing against other companies or investors.
- Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.
- 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.

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.
- 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.
- 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.
- 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.
- The FDA, EMA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.
- 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.
- 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.

- 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.

- 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.

- 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 current administration or other efforts, if any, to amend or challenge the ACA, will impact our business.

- 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.

- 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.

- 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 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 do not have a compliance program in place consistent with Federal agencies' guidance's on corporate compliance programs.

- 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.

- 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 Indian subsidiary may not be in compliance with laws applicable to it, and it may face penalties and fines imposed by the Indian government.

Risks Related 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.

- We do 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 our common stock.

- Future sales of a substantial number of shares of our common stock may cause the price of our common stock to decline.

- You may experience future dilution as a result of future equity offerings and exercise of put/call option under Option Agreements.

- 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.

- If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse opinion regarding our shares, our share price and trading volume could decline.

- Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to the Vyome Assets or its product candidates.

- Our principal shareholders, directors and executive officers own a significant percentage of our capital shares, and also have significant influence over our management.

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 Annual Report on Form 10-K, 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 Our 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 two products in India for sale by the subsidiary. Since our inception, 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.

We have incurred net losses in each period since our incorporation in August 2017. Our net losses were approximately $10.5 million for the year ended December 31, 2025. 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.

Cash and cash equivalents as of March 2, 2026 are anticipated to last until June 2027. We 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 up to June 2027. 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. In the future, we may 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 we conclude that there is 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, 2025, Vyome Technologies Inc. had U.S. federal net operating loss carryforwards of approximately $27.9 million. Of the total U.S. federal net operating loss carryforwards at December 31, 2025, losses generated beginning in 2020 (approximately $16 million) will carryover indefinitely. We had state net operating loss carryforwards of $27 million at December 31, 2025, and had foreign net operating loss carryforwards of approximately $2.2 million at December 31, 2024. In connection with the merger into Reshape LifeSciences, Inc. (renamed Vyome Holdings Inc.), we inherited approximately $230 million of federal net operating loss carryforwards, substantially all of which have no expiration. However, because of the Section 382 limitation discussed below, we have preliminarily calculated that we could only use approximately $400,000 of such net operating loss carryforwards annually.

Our net operating loss carryforwards are subject to review and possible adjustment by the taxing authorities. With certain exceptions (e.g. the net operating loss carryforwards), we are 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.

Our ability to utilize our 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, 2025 and 2024, 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 our 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 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 we 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 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 Assets. Our future capital requirements depend on many factors, including factors that are not within our control.

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 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.

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.

We may not realize all of the anticipated benefits of the Merger.

We 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 post-Merger 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;
- 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 our control, and any one of them could result in increased costs, decreased expected revenues and diversion of management time and energy, which could materially impact our business, financial condition, results of operations and cash flows. As a result, it cannot be assured that we will realize the full benefits anticipated from the Merger within the anticipated time frames, or at all.

We have incurred substantial direct and indirect costs as a result of the Merger and expect to incur substantial direct and indirect costs following the Merger.

We incurred 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, we also expect to incur substantial expenses as a result. These expenses could adversely affect our financial condition, results of operations and cash flows.

If the perceived benefits of the Merger do not meet the expectations of investors or securities analysts, the market price of our securities may decline.

If the perceived benefits of the Merger do not meet the expectations of investors or securities analysists, the market price of our securities may decline.

In addition, fluctuations in the price of our securities could contribute to the loss of all or part of a shareholder's investment. Prior to the Merger, there was no public market for our common stock. Accordingly, the valuation ascribed to us 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 our securities develops and continues, the market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our ability to commercialize the Vyome Assets or their corresponding product candidates, if approved;
- the status and cost of our marketing commitments for the Vyome Assets and their product candidates;
- announcements regarding results of any clinical trials relating to our product candidates;
- unanticipated serious safety concerns related to the use of the Vyome Assets or any of our product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to the Vyome Assets or our 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 Vyome 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 our ability to obtain patent protection for the Vyome Assets or the product candidates, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or shareholder litigation;
- our decision to initiate a clinical trial, not initiate a clinical trial or to terminate an existing clinical trial;

- our 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 our 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 we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- our 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 our 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 our or its competitors;
- changes in financial estimates by us or by any securities analysts who might cover its shares;
- fluctuation of the market values of any of our potential strategic investments;
- issuances of debt or equity securities;
- compliance with our contractual obligations
- sales of shares of our common stock by us or our shareholders in the future;
- trading volume of shares of our common stock;
- ineffectiveness of our internal controls;
- publication of research reports about us or our 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 our 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 our common stock, which could cause a decline in the value of its common stock. Price volatility of shares of our common stock 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 us, could cause us to incur substantial costs and divert management's attention and resources from our 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 our common stock.

Our operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly, and possibly annual, fluctuations. Our net loss and other operating results are affected by numerous factors, including:

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

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

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our 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 our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe 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 our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below the expectations of securities analysts and investors, resulting in a decline in the market price of shares of our common stock.

Certain of our 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 our officers and directors serve only part-time and are subject to conflicts of interest. Each of such officers and directors devote 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 our affairs. Because of these relationships, our officers and directors may be subject to conflicts of interest.

For example, Venkat Nelabhotla, our Chief Executive Officer, devotes approximately 40 hours per week to our 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 our directors, works full-time as an Associate Professor of Medicine at the Brigham and Women's Hospital and Harvard Medical School and dedicates his time to us 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, our Chief Financial Officer, works with us for 50% of his available time or a minimum of 80 hours per month. While our management has not, and we believe that our management 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 our business; accordingly, they may have conflicts of interest in allocating time between the separate business activities.

Risks Related to Our 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 fourth 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 outcome 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. 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 our 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 our 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 Our 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 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 our long-term sustainability and scalability. 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 our 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 our offices, clinical trial sites, key vendors and partners. Specifically, the COVID-19 pandemic impacted our ability to raise financing on desirable terms, and also led to reduced sales 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, we may in the future experience disruptions that could seriously harm our 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 our 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 could be materially adversely affected by the ongoing conflicts in various parts of the world.

As a result of military actions by the Russian Federation in Ukraine, as well as the ongoing conflicts in the Middle East, and related economic sanctions imposed by certain governments, our financial position and operations may be materially and adversely affected. As our ability to continue to operate is 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. In addition, disruption of critical infrastructure, supply chains and logistics, possible cyberattacks and data breaches from hostile actors who may take advantage of the chaos, increased cost and possible shortages of oil and natural gas and other necessary materials, interruption or loss of customers, counterparties or potential relationships with partners in affected regions, may result due to the destabilizing effects caused by such action. The extent of any potential impact is not yet determinable, however.

Risks Related to Our 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 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.

We generates all of our revenues from one customer, and loss of business from such customer could significantly harm our revenues and business.

We derive our revenues under the development and licensing agreement from one customer, Sun Pharma. Under the development and licensing agreement, we granted 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 us certain upfront fees and milestone payments, of which some milestone payments have already been realized as of December 31, 2025. We are also entitled to a royalty of 5% of the net sales of each product and payments against a few other future milestones. The supply and marketing agreement of dandruff products with Sun Pharma was terminated as of December 31, 2024.

Our ability to maintain close relationships with its existing customer will be essential to the growth and profitability of our 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 or our business 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.

We are 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.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired, which may adversely affect investor confidence in us and, as a result, the market price of our common stock.

As a public company, we are required to comply with the requirements of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, including, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We continue to develop and refine our disclosure controls and other procedures that are designed to ensure that information we are required to disclose in the reports that we file with the SEC are 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 our management, including our principal executive and financial officers.

We must continue to improve our internal control over financial reporting. We are required to make a formal assessment of the effectiveness of our internal control over financial reporting. To achieve compliance with these requirements within the prescribed time period, we have been engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our 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 we will not be able to conclude, within the prescribed time period or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. Moreover, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal additional deficiencies in our 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 our financial statements and reports, which would likely adversely affect the market price of our common stock. In addition, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC and other regulatory authorities.

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, 2025, 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. Historically, and as a private company, we had not maintained sufficient resources with various levels of accounting knowledge, experience, and expertise that are commensurate with our prospective financial reporting needs. These material weaknesses relate to the fact that we (1) 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 (2) do not have well defined segregate incompatible duties to reduce the risk of unauthorized transactions, and (3) insufficient accounting expertise to calculate certain technical matters. 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.

Although we have initiated various remediation efforts, 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 have hired an Interim Chief Financial Officer as of August 15, 2025 and will implement additional accounting procedures and controls as resources permit. We are evaluating improvements to our information technology environment to strengthen controls and processes.

- 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.

Risks Related to Our 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, we have had to abandon a few patent rights due to our 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 shares of our common stock. 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 our 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 have adopted 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 Item 1. "*Business — Governmental 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 current 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 and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, the current administration may reverse or otherwise change these measures. The order was revoked by President Trump on August 13, 2025. 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. On July 22, 2025, the EU Commission extended the validity of the adequacy decisions by an additional six months and amended such decisions to renew their term so that they will now expire on December 26, 2031.

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.

Our Indian subsidiary may not be in compliance with laws applicable to it, and it may face penalties and fines imposed by the Indian government.

We have not retained local counsel to assess whether our 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, our subsidiary, Vyome Therapeutics Limited, may be subject to adverse legal consequences, including but not limited to penalties and fines, which could adversely affect our business, financial condition or results of operations.

Risks Related 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; 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.

We do 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 our common stock.

We have not paid cash dividends on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. Since we do 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 our shares of common stock will appreciate or even maintain the price at which our shareholders have purchased it.

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

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our shares of common stock after the closing of the Merger, the trading price of our shares of common stock could decline and it could impair our ability to raise capital through the sale of additional equity securities. Certain of our shareholders are subject to lock-up provisions that restrict their ability to transfer shares of our common stock 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 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 and exercise of put/call option under Option Agreements.

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 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. Also, we have substantial additional shares of our common stock that may be issued if the put/call option under Option Agreements are exercised.

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 the Company authorized for the Board of Directors, 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 ("Reverse Stock Split"). 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 days, 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. On October 7, 2024, the Nasdaq Staff notified ReShape that it has regained compliance with Listing Rule 5550(a)(2) and that this matter is now closed.

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 granted us an extension through May 27, 2025 to regain compliance.

On May 28, 2025, we received a written notice from Nasdaq notifying us that our securities are subject to delisting from Nasdaq based on our continued non-compliance with Nasdaq Listing Rule 5550(b)(1). As of March 31, 2025, our stockholders' equity was $1.2 million. However (a) between June 3, 2025 and June 6, 2025, we sold 593,000 shares of common stock for gross proceeds of $3,642,564 pursuant to an equity distribution agreement with Maxim Group LLC in an "at-the-market" offering, as previously disclosed in the Company's prospectus supplement filed with the SEC on June 9, 2025, (b) on June 9, 2025, we completed an offering of 1,054,604 shares of common stock for gross proceeds of $2,636,510, as previously disclosed in the Company's Form 8-K filed with the SEC on June 12, 2025, and (c) on August 15, 2025, we effected a 1-for-4 reverse stock split of our common stock. As a result, as of the date of this filing, our stockholders' equity is greater than $2.5 million. The fact that our stockholders' equity is currently in excess of the minimum required for continued listing on The Nasdaq Capital Market does not guarantee that our securities will not be delisted from Nasdaq. We timely requested a hearing before a Nasdaq Hearings Panel, which will stay any suspension or delisting action pending the issuance of the Panel's decision following the hearing and the expiration of any additional extension period granted by the Panel.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse opinion regarding our shares, our share price and trading volume could decline.

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

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to the Vyome Assets or its product candidates.

We may issue additional equity securities to fund future expansion and pursuant to equity incentive or employee benefit plans. We may also issue additional equity for other purposes. These securities may have the same rights as shares of our common stock or, alternatively, may have dividend, liquidation or other preferences to shares of our common stock. The issuance of additional equity securities will dilute the holdings of existing shareholders and may reduce the share price of shares of our common stock. In addition, if our board of directors 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 our 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 we register their registrable securities under certain circumstances and will each also have piggyback registration rights for these securities. In addition, we are 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 Agreement 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 our securities.

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

Our principal shareholders, directors and executive officers own a significant percentage of our capital shares, and also have significant influence over our management.

Our directors, executive officers, holders of 5% or more of our capital shares and their respective affiliates beneficially own, in the aggregate, approximately 74.54% of our outstanding voting shares as of December 31, 2025. For a detailed discussion, see "*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*". This concentration of voting power may make it less likely that any other holder of shares of our common stock will be able to affect the way we are managed and could delay or prevent an acquisition of us 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.

Further, under the Merger Agreement, KKG Enterprises, LLC (an entity under the control of Krishna K. Gupta, who serves as Chairman of our board of directors) and Shiladitya Sengupta, each have a right to appoint 2 (two) directors on our board of directors, which in total comprises 6 (six) members. Accordingly, the aforesaid individuals will have control over the appointment of a majority of directors on our board of directors, and are directly or indirectly able to affect the decisions of the board, and, through their recommendations, of our shareholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data.

Managing Material Risks & Integrated Overall Risk Management

We have strategically integrated cybersecurity risk management into our broader risk management framework to promote a company-wide culture of cybersecurity risk management. This integration ensures that cybersecurity considerations are an integral part of our decision-making processes at every level. Our management team works closely with our IT department to continuously evaluate and address cybersecurity risks in alignment with our business objectives and operational needs.

Oversee Third-party Risk

Because we are aware of the risks associated with third-party service providers, we have implemented and are continuing to implement stringent processes to oversee and manage these risks. We conduct security assessments of all third-party providers before engagement and maintain ongoing monitoring to ensure compliance with our cybersecurity standards. This approach is designed to mitigate risks related to data breaches or other security incidents originating from third-parties.

Risks from Cybersecurity Threats

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing.

ITEM 2. PROPERTIES

We have approximately 110 square feet of office space in Princeton, New Jersey under an operating service agreement that expires on July 31, 2026. We also have approximately 150 square feet of office space in Cambridge, Massachusetts under two office service agreements that each expire on September 30, 2026.

We also lease approximately 3,000 square feet of office and laboratory in New Delhi, India under an operating lease that expires on December 31, 2026 and approximately 1,500 square feet of laboratory in New Delhi, India under an operating lease that expires on December 31, 2026.

ITEM 3. LEGAL PROCEEDINGS

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. The 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.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades on the Nasdaq under the symbol "HIND".

Number of Stockholders

As of March 2, 2026, there were approximately 13,200 holders of record of our common stock.

Dividend Policy

We have never paid cash dividends on our common stock. The board of directors presently intends to retain all earnings for use in our business and does not anticipate paying cash dividends in the foreseeable future. We do not have a dividend reinvestment plan or a direct stock purchase plan.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Part III, Item 12 of this Annual Report on Form 10-K.

Unregistered Sales of Equity Securities

None, except as previously disclosed.

Uses of Proceeds from Sale of Registered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Except for the historical information contained herein, the matters discussed in this "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in this Form 10-K are forward-looking statements that involve risks and uncertainties. The factors listed in Item 1A. "Risk Factors," as well as any cautionary language in this Form 10-K, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from those projected. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

On August 15, 2025, ReShape Lifesciences Inc. (now known as Vyome Holdings, Inc.) (the "Company") completed the merger pursuant to the Agreement and Plan of Merger, dated as of July 8, 2024, as amended (the "Merger Agreement"), by and among the Company, Raider Lifesciences Inc., a wholly owned subsidiary of the Company ("Merger Sub"), and Vyome Therapeutics, Inc. ("Vyome"). Pursuant to the Merger Agreement, Merger Sub merged with and into Vyome, with Vyome surviving the merger as a subsidiary of the Company (the "Merger"). As a result of the Merger, the Company was renamed "Vyome Holdings, Inc." and Vyome continued under its name as Vyome Therapeutics, Inc., in each case effective before the open of trading on August 15, 2025.

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, potentially an orphan drug designation program. The Company is planning to have discussions with the Food & Drug Administration (FDA) on a pivotal trial study design in the second quarter of 2026. The Company also has a Pre-Investigational New Drug application stage ophthalmic drops program, potentially an 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 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. One of the agreements for the supply of dandruff products to Sun Pharma was terminated in December 2024. The Company has also entered into an agreement with Sun Pharma for the development and licensing of MRT technology-based Luliconazole topical cream for skin fungal diseases for the Indian market.

The Company operates in two segments, biotechnology and pharmaceutical products. 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 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 various licensing agreements with Sun Pharma.

Recent Developments

Closing of the Merger

On August 15, 2025, the Company completed the merger pursuant to the Agreement and Plan of Merger, dated as of July 8, 2024, as amended (the "Merger Agreement"), by and among the Company, Raider Lifesciences Inc., a wholly owned subsidiary of the Company ("Merger Sub"), and Vyome Therapeutics, Inc. ("Vyome"). Pursuant to the Merger Agreement, Merger Sub merged with and into Vyome, with Vyome surviving the merger as a subsidiary of the Company (the "Merger"). As a result of the Merger, the Company was renamed "Vyome Holdings, Inc." and Vyome continued under its name as Vyome Therapeutics, Inc., in each case effective before the open of trading on August 15, 2025.

At the effective time of the Merger (the "Effective Time"), each share of common stock, par value $0.001 per share, of Vyome, and each share of preferred stock, par value $0.001 per share, of Vyome issued and outstanding immediately prior to the Effective Time (other than the shares that were owned by the Company, Vyome, or Merger Sub and shares that will be subject to put-call option agreements with certain stockholders of Vyome and Vyome's subsidiary Vyome Therapeutics Limited ("Vyome Limited") who are located in India) were converted into the right to receive a number of fully-paid and non-assessable shares of common stock of the Company, $0.001 par value per share according to a predetermined ratio; provided that the shares to be received by certain stockholders of Vyome and Vyome Limited located in India shall be subject to the put-call option agreements with the Company which entitles such holders to receive shares of Common Stock of the Company upon certain occurrences. In addition, each outstanding warrant, stock option, restricted stock award, stock grant or other equity award to purchase capital stock of Vyome were converted into right, warrants or equity awards to purchase a number of the Company's shares of common stock equal to the number of shares of Vyome common stock issuable upon exercise of such Vyome right, warrant or equity award multiplied by the predetermined ratio, with an exercise price, in the case of warrants and stock options, equal to the exercise price of such Vyome warrant or option divided by the predetermined ratio.

Immediately prior to the consummation of the Merger, the Company filed an Amended and Restated Certificate of Designation to Series C Convertible Preferred Stock (the "Series C Amendment").

The issuance of Common Stock in connection with the Merger was registered under the Securities Act of 1933, as amended, pursuant to the Company's registration statement on Form S-4 (File No. 333-282459) filed with the SEC on October 1, 2024, as amended on December 6, 2024, January 15, 2025, April 29, 2025, May 9, 2025 and May 14, 2025 and declared effective on May 14, 2025.

As set forth in the Merger Agreement, it was a condition to the closing of the Merger that The Nasdaq Stock Market ("Nasdaq") approve the initial listing application of the combined company so that the listing on The Nasdaq Capital Market will continue after the Merger. Nasdaq approved the initial listing application on August 6, 2025.

Changes in Officers and Directors

On August 13, 2025, in connection with the consummation of the Merger and, as required pursuant to, the Merger Agreement, Paul Hickey, Dan W. Gladney, Arda M. Minocherhomjee and Lori C. McDougal and Gary D. Blackford resigned from and ceased serving on the Board and any and all committees thereof, which resignations were effective upon the consummation of the Merger. In addition, effective upon the consummation of the Merger, Paul Hickey resigned as the President and Chief Executive Officer of the Company and Tom Stankovich resigned as the Chief Financial Officer of the Company.

In connection with the consummation of the Merger and pursuant to the Merger Agreement, on August 15, 2025, the Board elected and designated Krishna Gupta, Stash Pomichter, Shiladitya Sengupta, Venkateswarlu Nelabhotla, John Tincoff and Mohanjit Jolly (collectively, the "New Directors"), to serve on the Board effective immediately after the consummation of the Merger. Pursuant to the Merger Agreement and as previously disclosed, Krishna Gupta has been serving as the Board's Chairperson of the Company effective as of the consummation of the Merger.

Also on August 15, 2025, in connection with the consummation of the Merger, Venkateswarlu Nelabhotla was appointed as Chief Executive Officer of the Company and Robert Dickey was appointed as Interim Chief Financial Officer of the Company.

The Company entered into an agreement with Foresite Advisors, LLC, (the "CFO Agreement") governing the terms of Mr. Dickey's employment with the Company as its Interim Full-time Chief Financial Officer. The CFO Agreement provides for a one-year term, which may be extended by mutual written consent. The CFO Agreement may be terminated by either party with Cause, as defined in the agreement, upon 15 days' notice or without cause, upon 30 days prior written notice to the other party. The CFO Agreement provides for compensation of $15,000 per calendar month.

Closing of the Reshape Asset Sale

The Company completed the transactions contemplated under the Asset Purchase Agreement dated July 8, 2025, which was amended on April 25, 2025 (the "Asset Purchase Agreement"), with Ninjour Health International Limited, a company incorporated under the laws of the United Kingdom, which is an affiliate of Biorad Medisys Pvt. Ltd. (together, "Biorad"). Pursuant to the Asset Purchase Agreement, the Company sold its assets (excluding cash) to Biorad, and Biorad assumed substantially all of the Company's liabilities, for an agreed upon purchase price of $2.25 million in cash, subject to adjustment based on the Company's actual accounts receivable and accounts payable at the closing, compared to such amounts as of March 31, 2024.

Private Placement

Immediately after the Effective Time, the Company closed on the sale of an aggregate of 520,514 shares of the Company's Common Stock (the "Offered Shares") at a price of $11.02 per share pursuant to those certain subscription agreements entered into among, the Company, Vyome and the investors signatory thereto. Vyome, through its subsidiary Vyome Limited, also closed on the sale of 999 shares of Vyome Limited at a price per share of $937.14 which shares are subject to a put call option agreement with the Company. The shares were registered for resale in a Registration Statement on Form S-3, which was declared effective by the SEC on November 16, 2025.

Reverse Stock Split

On August 15, 2025, the Company effected a 1-for-4 reverse stock split of its Common Stock (the "Reverse Stock Split"). On July 24, 2025, the stockholders of the Company approved the proposal to authorize the Board of Directors of the Company (the "Board"), in its discretion, to amend the Company's Certificate of Incorporation, as amended, to effect a reverse stock split of the Company's Common Stock, at a ratio in the range of 1-for-2 to 1-for-5, such ratio to be determined by the Board and included in a public announcement. The Board subsequently approved the Reverse Stock Split at a ratio of 1-for-4 and on August 15, 2025 the Company filed a Certificate of Eighth Amendment (the "Certificate of Eighth Amendment") with the Secretary of State of the State of Delaware to amend the Company's Restated Certificate of Incorporation, as amended, and effected the Reverse Stock Split on August 15, 2025.

As a result of the Reverse Stock Split, each four shares of Common Stock issued or outstanding or held by the Company as treasury stock were automatically reclassified into one new share of Common Stock without any action on the part of the holders. Any fractional shares of Common Stock resulting from the Reverse Stock Split were rounded up to the nearest whole share and no stockholders received cash in lieu of fractional shares.

The Reverse Stock Split was primarily intended to bring the Company into compliance with the minimum bid price requirements for maintaining its listing on The Nasdaq Capital Market in connection with the Merger. Trading of the Company's Common Stock on The Nasdaq Capital Market continued on a split-adjusted basis when the markets opened on August 15, 2025, under the name Vyome Holdings, Inc. and trading symbol "HIND."

Amendments to Articles of Incorporation

On August 15, 2025, the Company filed (a) the Certificate of Eighth Amendment with the Secretary of State of the State of Delaware to effect the Reverse Stock Split after the close of trading on August 14, 2025, (b) Series C Amendment, and (c) a Certificate of Ninth Amendment (the "Certificate of Ninth Amendment") with the Secretary of State of the State of Delaware to amend the Company's Restated Certificate of Incorporation, as amended, to change its corporate name to Vyome Holdings, Inc.

Change of Auditor

As reported in the Current Report on Form 8-K filed by the Company on August 19, 2025, on August 18, 2025, Haskell & White LLP, was dismissed as the independent registered public accounting firm of the Company. Effective as of August 18, 2025 Kreit & Chiu CPA LLP was appointed to serve as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2025. The decision to change auditors was approved and recommended by the Company's Audit Committee and approved by its Board of Directors.

ATM Offering

On August 20, 2025, the Company entered into Amendment No. 1 (the "Amendment") to that certain Equity Distribution Agreement dated May 30, 2025 with Maxim Group LLC to act as the Company's exclusive sales agent with respect to the issuance and sale of up to $12,000,000 of the Company's shares of common stock, par value $0.001 per share, from time to time, in an at-the-market public offering (the "Offering"). The Amendment increased the amount that may be offered and sold in the Offering from $3,420,926 to $12,000,000.

Notes Purchase and Exchange Agreement with LICH and Remus

On December 17, 2025, the Company entered into a binding letter of intent (the "LOI") among, the Company, LiveChain, Inc. ("LICH") and Remus Capital Series B II, L.P. ("Remus") regarding a proposed transaction pursuant to which LICH, an indirect subsidiary of the Company, agreed to execute definitive agreements to acquire a senior secured convertible note (the "Note") issued by Sociometric Solutions, Inc., d/b/a Humanyze ("Humanyze") and held by Remus in exchange for the issuance to Remus of shares of common stock of LICH.

As of February 20, 2026, pursuant to the terms of the LOI, the Company entered into a Notes Purchase and Exchange Agreement (the "Agreement") by and among LICH, LICH AI Inc. (the "Buyer"), a subsidiary of LICH, and Remus to effectuate the transactions contemplated by the LOI. Pursuant to the Agreement, the Buyer will acquire senior secured convertible notes in the aggregate principal amount of $5,765,000 (the "Notes") issued by Humanyze and held by Remus. As consideration, LICH will issue to Remus 211,200,844 shares of its common stock, representing 25% of the fully diluted common stock of LICH immediately prior to Closing (as defined in the Agreement). The parties further agreed that immediately following the Closing, all or substantially all of the assets and operations of Humanyze shall be transferred to the Buyer, in full satisfaction of the amounts due and payable to the Buyer under the Notes.

The Agreement provides for the reservation for issuance of up to an additional 84,480,338 shares of LICH's common stock, representing 10% of the fully diluted common stock of LICH immediately prior to Closing, to key and future employees of LICH (the "Compensatory Shares"). LICH agreed to certain future issuances to Remus, upon issuance of shares by LICH as compensation in consideration of services provided to LICH which obligation to Remus shall terminate upon the earlier of (i) the second anniversary of the Closing; and (ii) the issuance of the Compensatory Shares.

Following the Closing, Remus agreed to ensure that Humanyze remains active and in good standing for purposes of servicing select existing debts, liabilities, and other obligations. In addition, the LICH board of directors and its CEO will use commercially reasonable efforts to raise capital as needed for LICH and/or the Buyer.

The Agreement contains customary representations, warranties and agreements by the parties and customary conditions to closing and obligations of the parties and indemnification provisions. In addition, the Agreement provides for certain termination provisions, including the right of either LICH or Remus to terminate the Agreement in the event that the closing of the transactions contemplated thereby shall not have occurred on or before a certain date (the "Outside Date"). On February 25, 2026, the parties amended the Agreement to update the Outside Date to March 8, 2026.

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. This arrangement was terminated in December 2024. We have a development and licensing agreement for MRT technology-based Luliconazole topical cream product for skin fungal diseases, from where we get revenues from milestone payments, royalties and the sale of a proprietary ingredient. These payments are recorded as service fee revenue in the period earned. We have occasionally received payments for milestones specified under the license of our products to Sun Pharma, but do not expect to receive any significant further milestone payments. We expect to continue to receive a minor amount of royalties under such licenses. Such revenues are part of our pharmaceutical segment.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, (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 and proprietary ingredients sold to Sun Pharma.

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 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.

Transactional fees

Fees paid to consultants and advisors in connection with the Merger, including the fair value of shares issued to such advisors are segregated as transactional fees.

Interest Expense

Interest expense results from the stated interest rates under our convertible notes. Borrowings under the notes carried an 8% coupon interest rate. All of the notes were converted into equity instruments in connection with the Merger.

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. All of the notes were converted into equity instruments in connection with the Merger.

Comparison of the years ended December 31, 2025 and 2024

Results of Operations

The following table summarizes our results of operations for the periods presented:

For the year ended December 31,

	For the year ended December 31,		
	2025	**2024**	**Change**
Revenue	$ 319,714	$ 256,944	$ 62,770
Cost of goods sold	(100,943)	(61,974)	(38,969)
Gross profit	218,771	194,970	23,801
Operating expenses:			-
Research and development	588,258	285,391	302,867
Depreciation and amortization	11,985	17,347	(5,362)
General and administrative	2,365,565	898,572	1,466,993
Transactional fees	7,705,533	-	7,705,533
Total operating expenses	10,671,341	1,201,310	9,470,031
Loss from operations	(10,452,570)	(1,006,340)	(9,446,230)
Other income (expense):			
Fair value adjustment	30,511	(238,931)	269,442
Other, net	90,987	3,814	87,173
Interest expense	(146,641)	(206,004)	59,363
Net loss	$ (10,477,713)	$ (1,447,461)	$ (9,030,252)

Revenues

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, 2025 and 2024 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 dandruff lotion and shampoo, but instead will receive a net service fee payment for sales of such products made by Sun Pharma. This arrangement was terminated in December 2024. We have a development and licensing agreement for MRT technology-based Luliconazole topical cream product for skin fungal diseases, from which we get revenues from milestone payments, royalties, and the sale of a proprietary ingredient.

Revenues for the years ended December 31, 2025 and 2024 are summarized as follows:

	2025	2024
Ingredient sales under Luliconazole Agreement	$ -	$ 75,147
Service fee for arrangements for sale of dandruff products	116,900	-
Royalty income related to above product sales	28,169	47,402
Licensing and milestone fees – Luliconazole	174,645	134,395
	$ 319,714	$ 256,944

Research and Development Expenses

Research and development expenses were $588,258 and $285,391 for the years ended December 31, 2025 and 2024, respectively. The increase in research and development costs was primarily due to resuming of R&D after the closing of the Merger with new funds raised by the Company.

General and Administrative Expenses

General and administrative expenses were $2,365,565 and $898,572 for the years ended December 31, 2025 and 2024, respectively. The increase was primarily due to an increase in legal, accounting, auditing, and related professional fees associated with preparing for the Merger, and the stock-based compensation of $577,128 related to stock options in the year ended December 31, 2025.

Interest expense

Interest expense was $146,641 and $206,004 for the years ended December 31, 2025 and 2024, respectively. The decrease was driven by the conversion of the convertible notes and debt in August 2025.

Fair value adjustment

The fair value adjustment related to the fair value of the Company's outstanding convertible notes was favorable/(unfavorable) $30,511 and $(238,931) for the year ended December 31, 2025, and 2024, respectively, reflecting the probability and timing of the Merger completion and resultant valuation considerations. As a result of the conversion of the Convertible Debt in connection with the Merger, there was no further fair value adjustments after August 2025.

Transactional fees

The Company incurred transactional and financial advisory fees costs for the year ended December 31, 2025, consisting of the fair value of shares issued to advisors of approximately $5.9 million and cash of approximately $1.8 million paid to advisors and professionals related to the Merger.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024:

For the year ended December 31,

	For the year ended December 31,		
Net cash provided by (used in):	2025	2024	Change
Operating activities	$ (3,748,853)	$ (614,136)	$ (3,134,717)
Investing activities	-	315	(315)
Financing activities	8,654,976	697,951	7,957,025
Other	(25,694)	1,127	(26,821)
Net increase in cash and cash equivalents	$ 4,880,429	$ 85,257	$ 4,795,172

During the year ended December 31, 2025, net cash used in operating activities was $3,748,853, consisting primarily of net losses of $10,477,713 less the non-cash charge for interest $130,659, fair value adjustment of convertible note debt of $(30,511), and stock compensation expenses of $6,576,822 and increase in prepaid expenses of $434,568, partially offset by an increase in other liabilities of $200,551 and accounts payable and accrued expenses of $171,342. The Company continues to operate under cost-efficient operations for capital efficiency.

During the year ended December 31, 2024, net cash used in operating activities was $616,436, consisting primarily of net losses of $1,447,461 less the non-cash charge for interest expense of $186,659 and an increase in accrued compensation and post-employment benefits of $197,935, partially offset by the loss on fair value adjustment of convertible debt of $238,931 and a decrease in accounts payable and accrued expenses of $58,861.

Financing Activities

During 2025 prior to the Merger and during 2024, we have primarily used the proceeds of the sale of our convertible notes and borrowings from Reshape to incrementally develop our biotechnology products and prepare the Company for an offering of its securities and activities related thereto. During 2025 prior to the Merger, cash provided by financing activities was principally from the net proceeds from the sale of common stock under Private Placement offering in the Company, proceeds from promissory notes issued by Reshape of $600,000 and bridge notes of $191,253 in VTI and VTL. We have operated under an austerity program for several years, delaying projects and payments until sufficient funds could be raised. We also settled certain liabilities in 2024 for accrued compensation and a vendor payment by issuing stock or stock options.

During the year ended December 31, 2024, cash provided by financing was $697,951, consisting primarily of approximately $667,010 from the sale of convertible notes and $30,900 of advances from affiliates.

As a result of the Merger, we were able to close on the funding from the Concurrent Financing (approximately $6.6 million) and subsequently from the ATM facility (approximately $1.3 million). The Company had approximately $4,982,000 of cash at December 31, 2025.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. As of December 31, 2025, we had a cash balance of approximately $4,982,000 and have operated under an austerity plan for several years. 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. 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.

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.

We believe that our existing cash, together with the proceeds from the private placement offering (Concurrent Financing) and proceeds from our ATM facility to date, will enable us to fund our operating expenses and capital expenditure requirements for at least 15 months. including the initiation of 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. From January 1, 2026, through March 12, 2026, the Company raised net proceeds of approximately $5,291,868 from the sale of common stock pursuant to the Sales Agreement with Maxim.

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 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.

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.

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.

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.

Licenses, employment agreements or other commitments

The Company leases offices and laboratory space in India, which were extended for a one-year period ending December 2026, with an automatic renewal for two years 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. We also have offices in Princeton, NJ, and Cambridge, MA, under 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 pre-clinical 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 that 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 a certain amount on change of control.

Critical Accounting Policies and Significant Judgments and Estimates

The following summarizes the most significant estimates impacting the financial statements. Refer to Note 2 for further information**.**

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. We have elected to account for the convertible notes using the fair value option in accordance with the guidance contained in ASC 815. 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 U.S. government zero-coupon bond, interpolated for the period that corresponds to the time to liquidity as at the valuation date. See Note 8 of the financial statements for additional information.

Stock options

The company accounted for the issuance of stock options in accordance with ASC 718, *Compensation-Stock Compensation*. 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. The Company expects to consolidate its various equity plans into a single plan during 2026.

Determination of the Fair Value of Equity-Based Awards

Prior to the Merger, there had 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, 2025 or 2024.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Vyome Holdings, Inc (f/k/a Reshape Lifesciences Inc.) and its subsidiaries

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Vyome Holdings, Inc (f/k/a Reshape Lifesciences Inc.) and its subsidiaries (the "Company") as of December 31, 2025 and 2024 and the consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the two years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024 and the results of its operations and its cash flows for each of the two years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2025.

/s/ Kreit and Chiu CPA LLP

Los Angeles, California
March 17, 2026

VYOME HOLDINGS, INC AND SUBSIDIARIES.
Consolidated Balance Sheets

(Amount in USD)	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 4,982,333	$ 101,904
Deferred offering costs	-	111,415
Prepaid expenses	336,687	9,039
Other current assets	119,301	79,688
Total current assets	**5,438,321**	**302,046**
Non-current assets		
Property and equipment, net	46,393	59,179
Intangible asset - shell company	314,191	314,191
Goods and service tax and other credits receivable	601,537	646,758
Prepaid insurance – long term portion	67,307	-
Right-of-use of asset, net	29,428	59,387
Total non-current assets	**1,058,856**	**1,079,515**
Total assets	**$ 6,497,177**	**$ 1,381,561**
Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable and accrued expenses	$ 1,286,683	965,607
Due to Affiliates	204,562	129,346
Operating lease liability - current portion	31,258	28,024
Salary and post-employment benefits payable	870,822	919,440
Other current liabilities	341,835	107,937
Convertible debt - current portion	-	3,589,410
Total current liabilities	**2,735,160**	**5,739,764**
Non-current liabilities		
Operating lease liability - net of current portion	-	32,830
Total non-current liabilities	**-**	**32,830**
Total liabilities	**$ 2,735,160**	**5,772,594**
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit)		
Common stock, 300,000,000 VHI shares authorized, 5,919,337 and 0 shares issued and outstanding at December 31, 2025 and 2024, respectively	5,919	-
Preferred stock of VTI, 16,000,000 shares authorized, 0 and 3,076 shares issued and outstanding as of December 31, 2025 and 2024, respectively	-	3
Additional paid in capital	90,078,579	51,084,877
Non-controlling interest in VTI; 20,000,000 common shares authorized, 1,481,598 and 386 shares issued and outstanding at December 31, 2025 and December 31, 2024	1,319,958	1
Accumulated deficit	(87,563,575)	(55,422,744)
Accumulated other comprehensive loss	(78,864)	(53,170)
Total stockholders' equity (deficit)	**$ 3,762,017**	**(4,391,033)**
Total liabilities and stockholders' equity (deficit)	**$ 6,497,177**	**$ 1,381,561**

The accompanying notes are an integral part of these consolidated financial statements.

VYOME HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31,

(Amount in USD)	**2025**	**2024**
Revenue	$ 319,714	$ 256,944
Cost of goods sold	(100,943)	(61,974)
Gross profit	**218,771**	**194,970**
Operating expenses		
Depreciation and amortization	11,985	17,347
Selling, general and administrative	2,365,565	898,572
Research and development	588,258	285,391
Transactional fees	7,705,533	-
Total operating expenses	**10,671,341**	**1,201,310**
Operating loss	(10,452,570)	(1,006,340)
Other income/(expense), net:		
Interest expense	(146,641)	(206,004)
Other income(loss), net	90,987	3,814
Fair value adjustment	30,511	(238,931)
Total other income (expense), net	**(25,143)**	**(441,121)**
Net loss	**(10,477,713)**	**(1,447,461)**
Net loss attributable to non-controlling interest	(215,706)	-
Net loss attributable to owners of Vyome Holdings, Inc.	**$ (10,262,007)**	**$ (1,447,461)**
Comprehensive Loss:		
Net loss	$ (10,477,713)	$ (1,447,461)
Other comprehensive loss:		
Foreign currency translation adjustments	(25,694)	1,127
Total comprehensive loss	**$ (10,503,407)**	**$ (1,446,334)**
Net Loss per share:		
Loss per share – basic and diluted	**$ (4.86)**	**$ (6,001.39)**
Weighted average number of shares outstanding	2,161,342	241

The accompanying notes are an integral part of these consolidated financial statements.

VYOME HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2025 AND 2024

(Amount in USD)	Common stock of VHI Shares	Common stock of VHI Amount	Preferred stock Shares	Preferred stock Amount	Additional Paid-in Capital	Accumulated Deficit	Common stock of VTI VTI Shares	Common stock of VTI Amount	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' equity (Deficit)
Balance at December 31, 2023	**-**	**$ -**	**2,968**	**$ 3**	**$ 47,855,359**	**$ (53,975,283)**	**386**	**$ 1**	**$ (54,297)**	**$ (6,174,217)**
Issuance of stock options in settlement of accrued compensation liability	-	-	-	-	$ 1,115,232	-	-	-	-	1,115,232
Issuance of shares in settlement of liability	-	-	86	-	$ 1,680,209	-	-	-	-	1,680,209
Conversion of note to preferred shares	-	-	22	-	$ 434,077	-	-	-	-	434,077
Shares issued	-	-	-	-	$ -	-	-	-	-	-
Net loss for the period	-	-	-	-	$ -	(1,447,461)	-	-	-	(1,447,461)
Foreign currency translation adjustment	-	-	-	-	$ -	-	-	-	1,127	1,127
Balance at December 31, 2024	**-**	**$ -**	**3,076**	**$ 3**	**$ 51,084,877**	**$ (55,422,744)**	**386**	**$ 1**	**$ (53,170)**	**$ (4,391,033)**

	Common stock of VHI Shares	Common stock of VHI Amount	Preferred stock Shares	Preferred stock Amount	Additional Paid-in Capital	Accumulated Deficit	Non controlling Interest VTI Shares	Non controlling Interest Amount	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' equity (Deficit)
Balance at December 31, 2024	**-**	**$ -**	**3,076**	**$ 3**	**$ 51,084,877**	**$ (55,422,744)**	**386**	**$ 1**	**$ (53,170)**	**$ (4,391,033)**
Stock based compensation	-	-	-	-	577,128	-	-	-	-	577,128
Issuance (and exercise) of warrants to investors	-	-	-	-	2,457,513	(2,457,513)	6,008,589	6,009	-	6,009
Conversion of certain preferred shares for new classes of preferred shares	-	-	1,238,604	1,239	19,420,072	(19,421,311)	-	-	-	-
Issuance of shares to advisors	-	-	-	-	5,899,318	-	376,256	376	-	5,899,694
Conversion of preferred stock to common stock	-	-	(1,241,680)	(1,242)	-	-	1,241,680	1,242	-	-
Conversion of notes payable to common stock	-	-	-	-	3,973,529	-	534,850	84,720	-	4,058,249
Shares of public company outstanding prior to merger	691,970	691			(691)					-
Net shares of VTI exchanged into VHI common stock	4,272,773	4,273	-	-	(268,074)	-	(6,536,093)	532,879	-	269,078
Shares issued in connection with concurrent financing	520,514	521	-	-	5,523,116	-	89,671	940,009	-	6,463,646
Shares issued in connection with ATM financing, net of costs	180,379	180	-	-	1,282,473	-	-	-	-	1,282,653
Exchange of Entitlement shares for common shares of VHI	233,741	234	-	-	29,338	-	(233,741)	(29,572)	-	-
Issuance of shares to marketing firm	19,960	20	-	-	99,980	-	-	-	-	100,000
Net loss for the period	-	-	-	-	-	(10,262,007)	-	(215,706)	-	(10,477,713)
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	(25,694)	(25,694)
Balance at December 31, 2025	**5,919,337**	**$ 5,919**	**-**	**$ -**	**$ 90,078,579**	**$ (87,563,575)**	**1,481,598**	**$ 1,319,958**	**$ (78,864)**	**$ 3,762,017**

The accompanying notes are an integral part of these consolidated financial statements

VYOME HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31,

(Amount in USD)	2025	2024
Cash flows from operating activities		
Net loss	$ (10,477,713)	**$ (1,447,461)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11,985	17,347
(Gain) loss on fair value adjustment of convertible debt	(30,511)	238,931
Non-cash accrued interest expense	130,659	186,659
Stock compensation expense - stock options	577,128	-
Stock compensation expense – common stock	5,999,694	-
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(434,568)	64,463
Other assets	75,982	78,742
Accounts payable and accrued expenses	171,342	(58,861)
Due to Affiliates	75,216	95,972
Post employment benefits	(48,618)	197,935
Other liabilities	200,551	12,137
Net cash used in operating activities	**(3,748,853)**	**(614,136)**
Cash flows from investing activities:		
Net proceeds from sale of fixed assets	-	315
Net cash used in investing activities	**-**	**315**
Cash flows from financing activities:		
Proceeds from issuance of convertible debt	191,253	667,009
Proceeds from promissory note issued by Reshape	600,000	-
Proceeds from sale of common stock pursuant to ATM	1,282,653	-
Proceeds from sale of common stock under Concurrent Financing, net of costs of $100,000 and deferred offering costs of $111,415	6,575,061	-
Proceeds from exercise of warrants	6,009	-
Advance from affiliates	-	30,942
Net cash provided by financing activities	**8,654,976**	**697,951**
Effect of exchange rate changes on cash and cash equivalents	(25,694)	1,127
Net increase in cash and cash equivalents	**4,880,429**	**85,257**
Cash and cash equivalents at beginning of the year	101,904	16,647
Cash and cash equivalents at end of the year	**$ 4,982,333**	**$ 101,904**
Supplemental non-cash and financing activities:		
Shares issued in settlement of liability to vendor	-	$ 1,680,210
Exchange of accrued fees to director for stock options	-	450,000
Exchange of accrued compensation for stock options	-	665,232
Incremental fair value of exchange of VTI preferred shares for new series of VTI preferred shares	$ 19,421,311	-
Conversion of preferred shares of VTI to common stock of VTI	1,242	-
Net liabilities assumed upon Merger with Reshape	149,735	-
Reclassification of debt and equity accounts to non-controlling interests	269,078	-
Conversion of debt into common stock	4,058,249	-
Fair value of issuance of warrants to preferred shareholders	2,457,513	-
Reclass of deferred offering costs to additional paid in capital	111,415	-
Exchange of entitlement shares for common shares of VHI	29,572	-

The accompanying notes are an integral part of these consolidated financial statements

1. Organization and principal activities

a) Merger Transaction:

Vyome Holdings, Inc. ("Vyome Holdings" or the "Company"), formerly known as Reshape Lifesciences, Inc. ("Reshape"), is the holding company for Vyome Therapeutics, Inc. ("VTI"), a Delaware corporation, and its subsidiary in India, Vyome Therapeutics Limited ("VTL") and are collectively referred to as "Vyome".

VTI signed a definitive merger agreement ("Merger") with Reshape Lifesciences, Inc. ("Reshape") in July 2024, and such transaction was completed on August 14, 2025. Immediately prior to the Merger, Reshape sold substantially all of its assets and operations to a third-party. Immediately prior to the Merger, all of the convertible notes and preferred stock of Vyome were converted into shares of common stock based upon negotiated values. As a result of the Merger, the Board of Directors and management team of Reshape resigned, the Board of Directors and management of VTI were installed, and the Company became a Nasdaq-listed company. Reshape changed its name to Vyome Holdings, Inc. and began trading under the ticker symbol "HIND". The Company will focus on Vyome's business of advancing the development of its immuno-inflammatory assets and on identifying additional opportunities in the world-class US-Indian innovation corridor for the global market.

The Company has accounted for the transaction as a reverse recapitalization with VTI as the accounting acquirer. Because VTI is the accounting acquirer, its historical financial statements became the Company's historical financial statements, and such assets and liabilities continued to be recorded at their historical carrying values. The impact of the recapitalization has been retroactively applied to all periods presented. Immediately after the closing of the Merger and the consummation of a private placement offering, the former holders of common stock of VTI owned, in the aggregate, approximately 88% of the common shares, with Reshape's shareholders immediately prior to the Merger owning approximately 12% of common shares outstanding.

b) Business

The Company is a Cambridge, Massachusetts-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 is a novel and patented topical gel to treat signs and symptoms of Malignant Fungating wounds and that can be a potential orphan drug designated program. The Company is planning to have discussions with the Food & Drug Administration (FDA) on the pivotal trial protocol in the second quarter of 2026. The Company had initiated a Phase II investigator-initiated trial in the first quarter of 2025 for VT-1953 and announced interim results in September 2025 and final results in December 2025. The Company also has a Pre-Investigative New Drug application stage ophthalmic drops program, a potentially orphan drug designated program, and a repurposed immune modulator to treat steroid-sparing anterior uveitis. Another late clinical-stage program, VB 1953, for moderate to severe inflammatory acne has successfully completed its Phase II clinical trial with positive read-outs, and this program is Phase III ready. The Company is also 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 using its patented technology after two such products successfully completed clinical testing in India. The Company has entered into a licensing and marketing agreement with the Sun Pharma group of companies in India ("Sun Pharma") to sell a family of novel topical anti-fungal products owned by the Company. The Company used third-party entities to manufacture the products. In December 2024, the licensing and marketing agreement was terminated.

The Company has entered into a Development and Licensing agreement for Luliconazole (an anti-fungal product) with Sun Pharma for additional development and commercialization in India. Sales of Luliconazole commenced in the third quarter of 2023 by Sun Pharma, and the Company earns royalties and milestone payments from this arrangement.

Since its inception, the Company has devoted substantially all its efforts to drug development, business planning, research and development, conducting clinical trials, 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 delays or 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.

c) Liquidity

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. For the years ended December 31, 2025 and 2024, the Company generated a net loss of $ 10,477,713 and $1,447,461, respectively. The Company's major sources of funds prior to the Merger have been through the sale of preferred stock and the issuance of convertible debt. In connection with the Merger, the Company sold shares of its stock (the "Concurrent Financing"). After the Merger, the Company has access to a financing facility to sell shares of common stock of the Company through an ATM facility, which may be accessed under certain circumstances– See Note 9. Further, the Company will be able to determine the timing of when planned clinical and pre-clinical operations will commence.

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, is necessary for the Company to continue operations. 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

As a result of the Merger transaction and private placement offering described in Note 9, the Company believes it has sufficient funds to finance the operating requirements for at least the next 12 months from the issuance of these Consolidated Financial Statements. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. Management continues to implement plans to manage the timing and amount of expenses and seek additional financing. However, there can be no assurance that these plans will be successful.

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 December 31, 2025 and 2024, 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"). Certain amounts in 2024 have been reclassified to conform to the 2025 presentation.

In August 2025, the Board of Directors of the Company approved a 5,000:1 reverse stock split. All share and per share numbers have been updated to reflect such a reverse stock split.

b) Segments

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 its chief executive officer. The Company determined it has two operating segments: (1) Pharmaceutical segment, 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. See Note 14.

As the Company's long-lived assets, except for the intangible asset, are substantially all located in India, and all of the Company's revenue and expenses related to the sale of products are derived from within India, no geographical segments are presented.

c) Basis of Consolidation

The Consolidated Financial Statements include the accounts of the Company, its majority-owned subsidiaries, VTL and VTI, and other wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in the consolidation.

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 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 loss, a separate component of stockholders' equity (deficit) 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/(gains) resulting from foreign currency transactions amounting to $25,694 and $(1,127) for the years ended December 31, 2025 and 2024, respectively, are included in the Consolidated Statements of Operations and Comprehensive Loss.

f) Cash and Cash Equivalents

Cash includes all highly liquid instruments with a maturity of three months or less when purchased. VTI and VHI maintain their cash balances in financial institutions that are insured by the Federal Deposit Insurance Corporation ("FDIC"). At various times during the year, such balances may exceed the FDIC limit. At December 31, 2025, the Company held approximately $4 million in one bank account, which exceeded the FDIC limit by approximately $3,750,000. The Company has not experienced any credit losses associated with its balances in such accounts. Cash held in the U.S. bank account of VTI as of December 31, 2025 and 2024, was $4,051,958 and $ 3,197, respectively. Cash held in India in VTL bank accounts as of December 31, 2025 and 2024, was $930,375 and $98,707, respectively.

g) Accounts Receivable, net

Accounts receivable are 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 creditworthiness. The Company follows *Financial Instruments - Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instrumen*ts, 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 on expected losses rather than incurred losses. Management determined that no allowance for doubtful accounts was necessary as of December 31, 2025 and December 31, 2024.

h) Property and equipment, net

Property and equipment 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 carry-forwards 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 carry-forwards over a 4-to-5-year period.

j) Intangible Assets

On August 21, 2021, Vyome acquired the majority of the outstanding shares, representing substantially all of the outstanding shares of preferred stock of Livechain, Inc. ("LICH") for $220,000. The total costs of the shares acquisition were $314,191. LICH is an inactive non-reporting shell ("Shell Company") that trades on the OTCID operated by OTC Markets Group under the ticker symbol LICH. As of the date of the acquisition of LICH and through December 31, 2025, 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 December 31, 2025 and 2024, management has determined that the value of the shares acquired in LICH is not impaired.

l) Non-Controlling interest

Noncontrolling interest reported as a component of equity on the consolidated balance sheets represents the equity interests not owned by the Company and is recorded for consolidated entities the Company controls, but which the Company owns less than 100%. The portion of the loss attributable to each such subsidiary that is held by outside investors is reported as Loss Attributable to Non-Controlling Interest in the Consolidated Statements of Operations and Comprehensive Loss.

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.

Substantially all revenues are from a single pharmaceutical company in India – Sun Pharma. The Company records sales of its dermatological products to Sun Pharma when performance obligations with Sun Pharma 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 transfer 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 has been immaterial historically. 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.

Net service fee payment and agent fees for sales of products made by Sun Pharma are recorded as service fee revenue in the period earned, and a based upon a percentage of invoiced amount Sun Pharma invoices its customers. Such revenues are recorded at the net amount received by the Company.

Pursuant to licensing and marketing contracts, the Company receives payments from Sun Pharma for the right to distribute the products ("royalties"). Such royalty payments are linked to the net sales value of the products by Sun Pharma 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 Operations and Comprehensive Loss.

The Company recognizes milestone payments under the license and marketing agreements when all performance obligations are completed, typically when there are no further steps required by the Company for that milestone.

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 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.

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. 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. The expected life of the stock options is not necessarily indicative of exercise patterns that may occur. The fair value measurement date for employee awards is the date of the grant.

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. 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. Prior to the Merger, the Company was a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical data regarding the volatility of a publicly traded set of peer companies. 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.

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.

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.

As the Company's common stock has not been publicly traded prior to the Merger, 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"*.

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 Statements. 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 the 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, 2025 and 2024, 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 years ended December 31, 2025 and 2024. 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

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 issued to investors using the fair value option in accordance with the guidance contained in 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. Pursuant to ASC 815-40-65-1(d), the Company made a one-time irrevocable election to apply the fair value option in ASC 825-10 for any liability classified convertible securities that are within the scope of ASC 825-10.

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 recorded 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 and promissory notes. 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 and promissory note instruments.

The following table sets forth the financial liabilities, measured at fair value, by level within the fair value hierarchy as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Level 3		
Convertible debt	$ -	$ 3,589,410

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, 2025 and 2024, 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 number of shares potentially issuable at December 31, 2024 upon conversion of the debt was not calculable and would be anti-dilutive.

The dilutive shares as of December 31, 2025 and 2024, not included in the dilutive loss per share calculation, are as follows:

	December 31, 2025	December 31, 2024
Stock options	2,763,180	280
Warrants	817	-
Preferred stock	-	3,076
Shares that are subject to put call option agreement for certain entitled VHI shares	1,481,598	-
Total	**4,245,595**	**3,356**

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 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 three 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.

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.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures,* which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity ("PBE") to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods or may apply the amendments retrospectively by providing the revised disclosures for all period presented. The Company has not yet adopted this new ASU, and it only impacts the Company's income tax disclosures with no impact to its operations, cash flows, or financial condition.

ASC 2024-03 requires public companies to disaggregate specific expense captions (such as cost of sales and general and administrative expenses) in the footnotes to the consolidated financial statements breaking them down into purchases of inventory, employee compensation, depreciation, intangible amortization and other categories. It is effective for annual periods beginning after December 15, 2026. The Company does not believe the adoption of this standard will have a significant impact on their consolidated financial statements.

3. Other current assets

Other current assets consist of the following:

	December 31, 2025	December 31, 2024
Advances to suppliers	$ 3,262	$ 12,134
Accounts receivable	325	2,294
Receivables from LICH	98,286	48,648
Others	17,428	16,612
Total other current assets	**$ 119,301**	**$ 79,688**
Prepaid expenses	$ 403,994	$ 9,039
Less long term prepaid insurance	67,307	-
Total prepaid expenses	$ 336,687	$ 9,039

Prepaid expenses consist primarily of prepaid directors' and officers' insurance.

4. Property and equipment, net

Property and equipment, net consist of the following:

	December 31, 2025	December 31, 2024
Buildings and Improvement	$ 122,609	$ 128,778
Computer and office equipment	42,360	52,412
Furniture & fixtures	13,622	13,865
Laboratory equipment	392,111	411,840
Total	570,702	606,895
Accumulated depreciation	(524,309)	(547,716)
Net fixed assets	**$ 46,393**	**$ 59,179**

Depreciation expense was $11,985 and $17,347 for the years ended December 31, 2025 and 2024, respectively.

5. Goods and services tax and other credits receivable

The Company's balance of goods and services tax and other credits receivable from government authorities as of December 31, 2025 and 2024, consists of the following:

	December 31, 2025	December 31, 2024
Tax deducted at source and tax collected at source receivable	$ 17,263	$ 3,283
Input goods and service tax credit	584,274	643,475
Total	**$ 601,537**	**$ 646,758**

6. Accounts payable and accrued expenses

Accounts payable and accrued expenses as of December 31, 2025 and 2024 consist of the following:

	December 31, 2025	December 31, 2024
Accounts payable	$ 647,533	$ 501,921
Accrued expenses	639,150	463,686
Total	**$ 1,286,683**	**$ 965,607**

The Company has a sole supplier of ingredients purchased by VTL

7. Salary and post-employment benefits payable

Salary and post-employment benefits payable as of December 31, 2025 and 2024, consist of the following:

	December 31, 2025	December 31, 2024
Salaries payable	$ 711,167	$ 777,578
Accrued leave encashment (note 13)	77,298	72,768
Accrued gratuity plan (note 13)	82,357	69,094
Total	**$ 870,822**	**$ 919,440**

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 129 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. Other current liabilities

Other current liabilities as of December 31, 2025 and 2024 consist of the following:

	December 31, 2025	December 31, 2024
Statutory dues payable	$ 8,323	$ 5,784
Advance from customer	26,086	38,358
Insurance premium payable	244,974	-
Others	62,452	63,795
Total	**$ 341,835**	**$ 107,937**

9. Convertible debt and Promissory Notes- ReShape

Convertible Debt

Commencing in October 2020 through February 2024, the Company began raising money through the issuance of a compulsorily convertible promissory note (the "Promissory Note") 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 $1,982,000 of secured convertible promissory notes (collectively, the "Promissory Notes") for a period of three years. 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 VTI'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 upon 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 the foregoing, if the conversion price of the Notes as determined pursuant to the foregoing (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 the Promissory 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 the Promissory Note remains outstanding, then the outstanding principal amount of the Promissory 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 of the Promissory Note 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 the Promissory Note has not otherwise been converted pursuant to the above, then, effective as of the Maturity Date, all outstanding principal and accrued and unpaid interest under the Promissory Note shall be automatically converted into Series D Preferred Stock, at a conversion price equal to the New Senior Preferred Conversion Price.

During 2023 and through September 2025, certain of the Promissory Notes reached their maturity date and were extended by an additional year. In connection with such extension, the conversion rate was amended from 0.80 to 0.75, and the liquidation preference was amended from three times to two times. All other terms remained the same. The Company accounted for such extension as a modification of the debt instrument. In August 2024, two of the Promissory Notes with an aggregate principal plus accrued interest of $ 434,077 were converted into 22 shares of Series D Preferred stock at $19,450 per share. All other noteholders whose Promissory Notes reached their initial maturity date agreed to the extension terms as noted above.

In July 2024, the Company began offering investors the opportunity to participate in a private placement offering, providing the investors the right to purchase shares of its common stock, bridge notes and warrants and other equity rights in VTI and VTL, some of which are dependent upon the completion of the Merger (the "Concurrent Financing"). An aggregate of 34 investors agreed to participate in such Concurrent Financing through the date of the Merger, for an aggregate of approximately $7.3 million, of which approximately $ 659,542 was received before closing of the Merger, in the form of bridge notes in VTI and VTL (the "Bridge Notes"). The Bridge Notes had similar terms to the Promissory Notes, except for a one-year term and were convertible at a 30% discount to the Merger valuation.

The fair value amount of the Promissory Notes and Bridge Notes and accrued interest is summarized as follows:

	December 31, 2025	December 31, 2024
Current portion		
Conversion rate at 70% of Merger Valuation	$ -	$ 487,206
Conversion rate at 75% of Qualified Financing	-	3,102,204
Total	**$ -**	**$ 3,589,410**

The Company has elected to record the Promissory Notes and Bridge Notes at fair value. Changes in the fair value of the Convertible Notes for the years ended December 31, 2025 and 2024 are summarized as follows:

	Year ended December 31, 2025	Year ended December 31, 2024
Balance, beginning of the period	$ 3,589,410	$ 2,930,888
Additional notes issued	191,253	667,009
Interest accrued	130,659	186,657
Change in fair value	150,673	238,931
Reclassification of accrued interest related to VTL notes to accrued expense	(3,746)	-
Conversion of notes and accrued interest to shares	(4,058,249)	(434,077)
Total	**$ -**	**$ 3,589,410**

In connection with the Merger, all of the Promissory Notes and Bridge Notes were converted into 534,850 and 86 shares of common stock of VTI and VTL, respectively. Since the terms of the conversion were as specified in the original Promissory Notes and Bridge Notes agreement and the debt was not modified or extinguished, pursuant to ASC 470-20-40-4 (as amended by ASU 2020-06), there is no recognition of any additional interest expense upon conversion.

Promissory Notes – ReShape ("Reshape Notes")

VTI entered into a note payable with Reshape for $400,000, of which payments under such note were received in several instalments from April 16, 2025 to June 5, 2025. The note bears interest at 8% per annum, was senior to any existing promissory or bridge notes, and matured on December 31, 2025. On June 28, 2025, the Company borrowed an additional $200,000 from Reshape pursuant to the same terms. The Reshape Notes were cancelled at the date of the Merger; however, the outstanding principal and interest were a part of the calculation of the relative shares of common stock of the Company retained by former Reshape shareholders at the Merger date. Changes in the fair value of the Reshape Notes for the year ended December 31, 2025, are summarized as follows:

	Year ended December 31, 2025
Balance, beginning of the period	$ -
Borrowings	600,000
Change in fair value	(181,184)
Elimination of promissory notes due to Merger	(418,816)
Total	**$ -**

Overall Debt

Interest expense on the above debt instruments was $130,659 and $186,247 for the years ended December 31, 2025 and 2024, respectively.

The fair value of the Promissory Notes, Bridge Notes, and Reshape Notes, and Reshape 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 U.S. government zero-coupon bond, interpolated for the period that corresponds to the time to liquidity as at the valuation date, for the years ended December 31, 2025 and 2024 are as follows:

	December 31, 2025	December 31, 2024
Adjusted Interest rate	4.41% to 4.45%	4.16% to 4.40%
Time to Financing Date	1-3 months	6-8 months

10. Common Stock and Preferred Stock

Authorized Capital

VTI 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. In June 2024, the number of authorized shares of preferred stock increased to 16,000,000 shares. In August 2025, the Board of Directors of the Company approved a 5,000:1 reverse stock split. In August 2025, VTI amended the Articles of Incorporation of the Company to authorize three new series of preferred stock, with similar rights as the existing shares of preferred stock:

a. Series D-1 – 23,658 shares authorized with an "original issuance price" of $8.874 per share

b. Series D-2 – 315,256 shares authorized with an "original issuance price" of $5.886 per share

c. Series Seed-1 – 900,000 shares authorized with an "original issuance price" of $0.936 per share

The Company has 300,000,000 shares of common stock authorized.

VTI Common stock transactions

In August 2025, VTI issued 376,256 shares of common stock to certain advisors and consultants. The fair value of such shares of approximately $5.9 million is recorded as a Transactional Fee in the accompanying Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2025.

In August 2025, VTI issued warrants to certain preferred shareholders, who agreed to participate in the Concurrent Financing, to purchase 6,008,589 shares of VTI common stock at $0.001 per share. The warrants were immediately exercised, and VTI received $6,009 in proceeds from such exercise. The fair value of the warrants, or $2,457,513, is considered a shareholder transaction and recorded analogous to a "deemed dividend" in the Consolidated Statement of Stockholders' Equity.

In August 2025, all of the preferred stock outstanding was converted into 1,241,680 shares of VTI common stock.

As discussed in Note 8, all of the outstanding VTI's Promissory Notes and Bridge Notes and related accrued interest were converted into 534,850 shares of VTI common stock.

VTI Preferred stock

In August 2025, several preferred shareholders were issued shares of a new series of preferred stock in exchange for their current holdings in earlier issued series of preferred stock as follows:

a. 11 shares of Series D preferred stock exchanged into 23,658 shares of Series D1 preferred stock

b. 96 shares of Series D preferred stock exchanged into 315,256 shares of Series D2 preferred stock

c. 203 shares of Series D preferred stock exchanged into 900,000 shares of Seed Series-1 preferred stock

Such shareholders received an aggregate of 1,238,604 additional shares of preferred stock. The estimated fair value of such additional preferred shares was $19,421,311 is considered a shareholder transaction and recorded analogous to a "deemed dividend" in the Consolidated Statement of Stockholders' Equity.

As a result of the Merger transaction, all shares of preferred stock were converted into common stock.

At December 31, 2024, the Company had the following preferred stock issued and outstanding:

Series	Number of shares issued	Price	Aggregate Liquidation Preference at December 31, 2024
Series seed	217	$ 4,150	$ 1,332,687
Series A	519	$ 6,100	4,671,576
Series B	194	$ 12,350	3,529,173
Series B-1	296	$ 12,350	5,413,544
Series C	890	$ 13,200	17,339,432
Series C-1	106	$ 13,200	2,073,278
Series D	854	$ 19,450	23,437,007
Total	**3,076**		**$ 57,796,697**

The significant terms of the preferred stock were 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 prior to the Merger. As of December 31, 2024, cumulative dividends in arrears for all classes' preferred shares were approximately $18,100,000.

Each share of preferred stock shall be convertible at the option of the holder, without the payment of additional consideration, into common stock at the conversion price as defined in VTI's Certificate of Incorporation. 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 of 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 B-1 and C-1. Part of the amount invested by series B-1 and C-1 preferred stock as mentioned in the shareholders' agreement, ranks junior to other preferred stockholders; however, ranks 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.

VHI Stock transactions

At the Merger date, there were 8,161,761 common shares of VTI outstanding, of which 6,843,451 of such VTI common shares were exchanged into 4,272,773 shares of VHI common stock as merger consideration pursuant to the Exchange Ratio specified in the Merger Agreement. The remaining VTI 1,318,310 common shares remain outstanding, against which certain VHI common shares are entitled as merger consideration ("Entitlement Shares")

At the Merger date, there were 691,970 shares of VHI common stock outstanding, which were held by the former Reshape shareholders, and continue to be outstanding at December 31, 2025. The net liabilities of Reshape assumed at the Merger date were approximately $244,000.

A Private Placement offering in the Company and a Share Subscription in VTL closed shortly after the Merger (see Note 8), and resulted in VTL receiving gross proceeds of $940,009 from the sale of 999 shares of VTL and the Company receiving $5,735,052 from the sale of 520,514 shares of VHI common stock, inclusive of the amounts received in advance in the form of bridge notes (see Note 7). Net of expenses of $100,000, the Company received an aggregate of $6,575,061. The amount recorded with the consolidated statement of stockholders' equity of $6,463,646 includes the offset of the deferred offering cost of $111,415.

The Company issued 19,960 shares of common stock to a marketing vendor in December 2025, and recorded an expense of $100,000 in selling, general and administrative expenses.

At The Market Offering

On August 20, 2025, the Company entered into Amendment No. 1 to the Equity Distribution Agreement dated May 30, 2025 (the "Sales Agreement" or "ATM") with Maxim Group LLC ("Maxim") to act as the Company's exclusive sales agent with respect to the issuance and sale of up to $12,000,000 of the Company's shares of common stock from time to time, in an at-the-market public offering (the "Offering"), less a 3% discount. The Company has targeted a certain floor price and maximum daily sales as a percentage of daily trading volume at which it will sell shares under the Sales Agreement. From August 20, 2025 to December 31, 2025, the Company sold 180,379 shares of common stock at prices between $4.90 and $11.40 per share under the Equity Distribution Agreement, resulting in net proceeds of $1,282,653.

Entitlement shares

In connection with the Merger, three put/call option agreements were put in place.

a. The first put/call option agreement is between the Company and certain investors in VTI. Through this agreement, 1,318,310 shares of common stock held by Indian stockholders of VTI be exchanged for 825,307 entitled shares of VHI common stock pursuant to the put/call exercise in the future as per the terms of the agreements.

b. The second put/call option agreement is between the Company's Indian subsidiary, VHI, and investors in the bridge investments that came in the form of Compulsory Convertible Debentures that were converted to 86 shares in the Indian subsidiary at the Merger closing. Those shares are to exchanged for 800,361 entitled shares of common stock of VHI pursuant to the put/call exercise in the future as per the terms of the agreements.

c. The third put/call option agreement is between the Company's Indian subsidiary, VHI, and investors for the concurrent (concurrent to Merger closing) financing for subscription of 999 shares in the Indian subsidiary. Those shares are to be exchanged for 89,671 entitled shares of common stock of VHI pursuant to the put/call exercise in the future as per the terms of this agreement

VHI may exercise its call options for the specified shares of VTI or VTL in the above three option agreements upon certain defined liquidation events. The investors may exercise their put options for the purchase of their entitled shares of the Company upon certain defined financing and/or liquidation events, in all cases subject to approval by the Board of Directors of the Company and VTI. The consideration to be paid for such put/call options is based upon pro rata "liquidation event" proceeds or certain specified amounts, and in certain investor cases, for the exchange of common stock of VHI. These put/call options are equity classified since all actions under the agreements are subject to the Company's control. Upon exercise, the Company will recognize a "deemed dividend" for the excess of the fair value of the stock received at such date, less its historical cost.

Between the Merger date and December 31, 2025, 233,695 of entitlement shares held by VTL shareholders and 46 entitlement shares held by VTI shareholders were exchanged for 233,741 shares of VHI common stock.

Since the shares discussed above are outstanding shares issued by subsidiaries of the Company, they are classified as non-controlling interests. As of December 31, 2025, approximately 10% of VTL and 16% of VTI are owned directly by shareholders other than VHI in VTI and by VTI in VTL.

The non-controlling interest is summarized as of December 31, 2025, as follows:

	Entitled shares	Historical Cost Amount
VTI Shareholders	825,261	$ 540,488
VTL Noteholders	566,666	55,167
Investors in VTL common stock through the Concurrent Financing	89,671	940,009
	1,481,598	1,535,664
Loss attributable to non-controlling interest for the year ended December 31, 2025		(215,706)
Non-controlling interest at December 31, 2025	**1,481,598**	**$ 1,319,958**

11. Stock-Based Compensation

VTI has two stock option plans. There is also a legacy Reshape plan that was still in effect at the time of the Merger. The Company is in the process of converting these plans into a comprehensive VHI plan. All share amounts have been adjusted to reflect the reverse stock split discussed above.

2018 ESOP PLAN

On December 14, 2018, VTI authorized an Employee Stock Option Plan 2018 (the "ESOP Plan") under which 1,719,720 shares of common stock were reserved 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, including employees remaining in employment during the vesting period, and directors and consultants continuing to render 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 the optionee's tenure with the VTI. However, the exercise period lapses ninety (90) days after the employee, director, or consultant leaves the Company.

The last issuance of an option under the ESOP Plan was in 2024. 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, using 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	$ 4,500

The summary of stock options activity for the years ended December 31, 2025 and 2024, is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Time to Expiry
Outstanding as of December 31, 2023	165	$ 2,750.00	4.0 years
Granted during 2024	129	4,500.00	9.5 years
Expired during 2024	(14)	5,000.00	
Exercised during 2024	-	-	
Outstanding as of December 31, 2024	280	$ 3,451.03	6.0 years
Granted during year ended December 31, 2025	-	-	-
Expired during year ended December 31, 2025	(1)	2,400.00	-
Exercised during year ended December 31, 2025			
Outstanding as of December 31, 2025	279	$ 3,453.05	5.8 years
Exercisable as of December 31, 2024	280	$ 3,451.03	6.7 years
Exercisable as of December 31, 2025	279	$ 3,453.05	5.6 years

The following outlines the outstanding and vested stock options by exercise price as of December 31, 2025, and December 31, 2024.

Exercise Price	Number of Options Outstanding and fully vested – December 31, 2025	Number of Options Outstanding and fully vested – December 31, 2024
$2,400.00	140	140
$4,500.00	131	131
$5,000.00	8	9
Total	**279**	**280**

In June 2024, VTI granted options to purchase 129 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 recognized no stock-based compensation expense in the Company's Consolidated Statements of Operations and Comprehensive loss for the year ended December 31, 2025, and 2024 under the ESOP Plan. As of December 31, 2025, 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, 2025. The intrinsic value of vested and outstanding stock options was zero.

2025 Stock Option Plan

In August 2025, VTI authorized an Employee Stock Option Plan 2025 (the "2025 Plan") under which 2,800,000 shares of common stock were reserved for issuance to directors, consultants, and employees of the Company. The 2025 Plan entitles directors, consultants, and employees of the Company to purchase common stock of VTI at a stipulated price, subject to compliance with vesting conditions including employees remaining in employment during the vesting period and directors and consultants continuing to render 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.

In August 2025, VTI issued stock options to employees, consultants, board members, and others to purchase 2,705,779 shares of VTI common stock at an exercise price of $0.41 per share, which vest immediately and 57,122 shares of VTI common stock at an exercise price of $0.41 per share, which vest over a one-year period from the date of grant to employees.

The Company has estimated the fair value of the 2025 stock option awards as of the date of grant by applying the Black-Scholes option-pricing model using the following assumptions:

Risk-free interest rate	4.41%
Expected term	5 years
Expected volatility	54%
Expected dividends	0
Grant date fair value of common stock	$ 0.41

The summary of stock option activity of the 2025 Plan for the year ended December 31, 2025 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Time to Expiry
Outstanding as of December 31, 2024	0	$ -	-
Granted during year ended December 31, 2025	2,762,901	$ 0.41	6.0 years
Expired during year ended December 31, 2025	-	-	
Exercised during year ended December 31, 2025	-		
			-
Outstanding as of December 31, 2025	2,762,901	$ 0.41	5.6 years
Exercisable as of December 31, 2025	2,729,580	$ 0.41	5.6 years

The Company recognized $577,128 of stock-based compensation expense which is included in Research and Development and Selling, General and Administrative Expenses based on allocation in the Company's Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2025. As of December 31, 2025, there is a future compensation cost of $7,045 to be recognized related to stock options granted under the 2025 Plan over the next 10 months. The intrinsic value of vested and outstanding stock options was approximately $8.3 million.

Legacy Reshape Plans

At the time of the Merger, the following fully vested options and warrants were outstanding.

- Stock options to purchase 1 share of common stock, which expired prior to December 31, 2025.
- Warrants to purchase 817 shares of common stock at exercise prices ranging from $0.92 to $46,400.00 per share. The warrants will expire at various times from June 2026 to December 2029.

12. Income taxes

The Company generated a current taxable loss for the years ended December 31, 2025 and 2024, and therefore, the only current income taxes payable were certain minimum taxes. The effective tax rate for the years ended December 31, 2025, and 2024 was zero 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, summarized as follows.

For the Years Ended December 31,

	2025	2024
Tax benefit at the federal statutory rate	21%	21%
State tax, net of federal benefit	7%	7%
Permanent differences – principally unrealized gains/losses and expenses related to warrant issuance	(13)%	(3)%
India tax rate differential and other	(3)%	(1)%
Change in valuation allowance	(12)%	(24)%
Effective income tax rate	0%	0%

Deferred tax assets at December 31, 2025 and 2024 are summarized as follows:

	December 31, 2025	December 31, 2024
VTI - net operating loss carryforwards	$ 7,828,389	$ 5,391,381
Stock options	301,178	139,582
Accrued compensation	146,458	111,424
Accrued expenses	62,684	37,101
Interest	-	133,526
Research and development tax credits	78,388	78,388
VTL - net operating loss carryforwards and other	1,212,217	2,018,472
Reshape – net operating loss carryforwards	65,147,880	-
VHI – net operating loss carryforwards	407,981	-
Total deferred tax assets	75,194,175	7,909,873
Less: valuation allowance	(75,194,175)	(7,909,873)
Net deferred tax assets	$ -	$ -

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, 2025 and 2024. 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 $67,300,000 and $379,000 for the years ended December 31, 2025, and 2024, respectively, principally due to the net operating losses acquired in the Merger – see below for discussion of limitation related thereto.

As of December 31, 2025, VTI has net operating loss carry-forwards of approximately $28.0 million in the United States, which will expire as follows: $16.1 million has no expiration date, $10.2 million expires in 2039, and $1.7 million expires in 2038. Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carry-forwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carry-forwards. 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 carry-forward 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.

At the date of the Merger, Reshape had approximately $230 million of net operating loss carryforwards, the majority of which has no expiration. However, utilization of such net operating losses will be limited (pursuant our preliminary the Internal Revenue Code Section 382 analysis) to approximately $400,000 per year.

As of December 31, 2025, VTL has approximately $2.3 million USD equivalent of net operating loss carry-forwards.

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.

13. Leases

The Company leases offices and laboratory space in India, which were automatically extended for two one-year periods ending December 2026, with payments ranging from $2,500 to $2,900 per month. The Company intends to renew the leases through December 2026 as allowed under the lease agreement. In the U.S., the Company has month-to-month shared space arrangements, and therefore, there is no requirement to record a right of use asset and related liability.

Operating leases are presented in the Company's Consolidated Balance Sheets as right-of-use assets, net, operating lease liability– current portion, and operating lease liability, net of current portion. 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 $33,000 in the year ending December 31, 2026. The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of December 31, 2025:

Lease payments – 2026	$ 32,820
Total undiscounted operating lease payments	32,820
Less: Imputed interest	(1,562)
Present value of operating lease liabilities	**$ 31,258**
Current portion of lease liability	$ 31,258
Long-term portion of lease liability	-
Total lease liability	**$ 31,258**

	As of December 31, 2025	**As of December 31, 2024**
Weighted average remaining lease term in years	1.0	2.0
Weighted average discount rate	8.0%	8.0%

The Right of Use Asset on December 31, 2025 of $29,428 will be amortized over the 1 year remaining under the lease term. The Right of Use Asset balance on December 31, 2024, was $59,387. Rent expense was approximately $37,000 and $36,000 for the years ended December 31, 2025 and 2024 respectively.

14. Commitments and contingencies

a) 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 a liability of $1,680,210 into 86 shares of Series D preferred shares (based upon the then estimated fair value of such shares). In June 2024, the Company increased its authorized shares of preferred stock and issued 86 shares of Series D preferred stock to settle this liability.

b) 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 six 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. A roll forward of the liability balance for the years ended December 31, 2025 and 2024 are as follows:

	Year ending December 31, 2025	Year ending December 31, 2024
Obligation recognized in balance sheet:		
Beginning of period	$ 69,094	$ 90,886
Benefits paid	(10,773)	(14,056)
Expenses charged to profit or loss	24,533	(9,430)
Currency translation differences	(497)	(2,323)
Interest on gratuity payable	-	4,017
End of the Year	$ 82,357	$ 69,094

c) 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, 2025 and 2024 are as follows:

	Year ending December 31, 2025	Year ending December 31, 2024
Obligation recognized in balance sheet:		
Beginning of period	$ 72,768	$ 84,647
Benefits paid	(11,875)	(3,920)
Expenses charged to profit or loss	16,335	(5,669)
Currency translation differences	70	(2,290)
End of the Year	$ 77,298	$ 72,768

d) 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 principally charged to research and development expense in the consolidated statements of operations and comprehensive 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, 2025 and 2024 was approximately $1,200 and $1,600, respectively.

e) 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, 2025 and 2024, the Company had no outstanding claims or litigation and had no liabilities recorded for loss contingencies.

15. 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 years ended December 31, 2025 and 2024:

	For the year ended December 31, 2025			For the year ended December 31, 2024		
Amount in USD	**Biotechnology**	**Pharmaceutical**	**Total**	**Biotechnology**	**Pharmaceutical**	**Total**
Revenues	$ -	$ 319,714	$ 319,714	$ -	$ 256,944	$ 256,944
Gross margin	-	218,771	218,771	-	194,970	194,970
		-				
Operating expenses:		-				
Depreciation and amortization	11,985	-	11,985	17,347	-	17,347
Selling, general and administrative	2,279,978	85,587	2,365,565	837,045	61,528	898,572
Transactional fees	7,705,533	-	7,705,533	-		-
Research and development	534,394	53,864	588,258	245,713	39,677	285,391
Total Operating expenses	**10,531,890**	**139,451**	**$ 10,671,341**	**1,100,105**	**101,205**	**$ 1,201,310**
Other Income (expenses)						
Interest expense	(146,641)	-	(146,641)	(206,004)	-	(206,004)
Fair value adjustment	30,511	-	30,511	(238,931)	-	(238,931)
Other income (loss), net	90,987	-	90,987	3,814	-	3,814
Other expenses	**(25,143)**	**-**	**$ (25,143)**	**(441,121)**	**-**	**$ (441,121)**
Net income (loss)	**$ (10,557,033)**	**$ 79,320**	**$ (10,477,713)**	**$ (1,541,226)**	**$ 93,765**	**$ (1,447,461)**
Assets of segment	$ 6,496,852	$ 325	$ 6,497,177	$ 1,379,267	$ 2,294	$ 1,381,561

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, 2025 and 2024 are derived from Sun Pharma, a significant pharmaceutical company based in India. Revenues for the years ended December 31, 2025 and 2024 are summarized as follows:

	Year ending December 31, 2025	Year ending December 31, 2024
Service fee for arrangements for sale of Dandruff products	$ -	$ 75,147
Licensing and milestone fees – Luliconazole	116,900	-
Sale of products	174,645	134,395
Royalty income related to above product sales	28,169	47,402
Total	$ 319,714	$ 256,944

In December 2020, the Company entered into a licensing contract for a product with Sun Pharma, whereby the Company would be entitled to development and sales-based milestones and royalties on future sales of the product by Sun Pharma. No development milestones, sales-based milestones or royalties have been received under this license during the year ended December 31, 2024, and $116,900 was earned during the year ended December 31, 2025.

During 2024, 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. This arrangement was terminated in December 2024.

16. 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 and Comprehensive Loss amounting to approximately $100,000 for each of the years ended December 31, 2025 and 2024. The amount outstanding to such Directors as of December 31, 2025 and 2024 is approximately $200,000 and $100,000, respectively, which is included in 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 $260,000 for each of the years ended December 31, 2025 and 2024. The amount outstanding as of December 31, 2025 and 2024 to the CEO is $323,066 and $282,777, 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 approximately $5,000 and $15,000 at December 31, 2025 and 2024, respectively. This is included Due To Affiliates in the accompanying Consolidated Balance Sheets and is yet to be repaid as of the date of these financial statements.

17. Subsequent events

For the consolidated financial statements as at and for the year ended December 31, 2025, 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 as described below.

From January 1, 2026, through March 17, 2026, the Company raised net proceeds of approximately $5,291,000 from the sale of common stock pursuant to the Sales Agreement with Maxim (see Note 9).

In January 2026, the Company issued 9,646 shares of VHI common stock to a vendor.

In February 2026, VHI issued stock options to employees, board members and consultants to purchase 1,725,211 shares of common stock at $0.66 per share and 75,400 shares of common stock at $4.97 per share. The majority of such shares vest immediately, with the remaining vesting over various periods up to 4 years. These options have a 10-year life. Shares previously outstanding from the VTI 2025 plans will be cancelled.

In February 2026, a newly formed subsidiary of LICH ("LICH sub") purchased a note receivable from an investor in an AI company called "Humanyze" in exchange for 25% of its holdings in LICH. Such investor is also an investor in the Company, and a principal of such investor is a member of both Humanyze and our Board of Directors. LICH sub, using the default provision of the note receivable, acquired all of the assets of Humanyze in settlement of the note receivable. LICH sub intends to hire personnel, raise funds and advance the operations of Humanyze.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

During the last two fiscal years, we have had no disagreements with our accountants on accounting and financial disclosure. On August 18, 2025, Kreit & Chiu CPA LLP was appointed to serve as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2025. The Company's financial statements had previously been audited by Haskell & White LLP.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), defines the term "disclosure controls and procedures" as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. An internal control material weakness is a significant deficiency, or aggregation of deficiencies, that does not reduce to a relatively low level the risk that material misstatements in financial statements will be prevented or detected on a timely basis by employees in the normal course of their work. An internal control significant deficiency, or aggregation of deficiencies, is one that could result in a misstatement of the financial statements that is more than inconsequential. In making its assessment of internal control over financial reporting management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, and determined that our internal control over financial reporting was not effective at a reasonable assurance level due to the following material weaknesses in our internal control over financial reporting identified during the prior year that have not yet been remediated.

Control Environment: During most of 2025, the Company has insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls over the financial reporting process. Further, we are in the process of developing a comprehensive policies and procedures manual designed to establish internal controls over financial reporting to reduce the risk of publishing materially misstated financial statements. We use third-party specialists to help support complex accounting and financial reporting matters, have hired our CFO in August 2025 and have begun to outline a plan to address such matters. However, during the majority of 2025, we did not have sufficient procedures in place.

Journal Entry Access and Review: The Company did not have effective processes to ensure that all journal entries were properly approved prior to being posted to the general ledger. Furthermore, a segregation of duties conflict is present as the Sr. Accounting Manager has the ability to both prepare and post journal entries to the general ledger. As a result, it was concluded that there is material weakness in the design and operating effectiveness of internal controls over access and reviews of journal entries.

Information Technology ("IT") Access Change and IT Security: A segregation of duties conflict is present as access, change management and other IT security risks to the Company's information technology systems are not monitored or reviewed on a timely basis. Further, our current systems do not contain sufficient cybersecurity controls and safeguards. This material weakness resulted from the aggregation of various control deficiencies.

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.
- Designing and implementing formal processes, policies and procedures supporting our financial close process. We are in the process of documenting such policies and procedures.
- Design a formal review of a monthly journal entry report to ensure journal entries are appropriately approved within a timely manner.
- Evaluating proposals to upgrade IT security and processing protocols.

Management's Report on Internal Control Over Financial Reporting

The Company's management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control-Integrated Framework (2013)* issued by the Committee of sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, the Company's management concluded that due to the material weakness described above, its internal control over financial reporting was not effective as of December 31, 2025.

Under SEC rules, because we are a non-accelerated filer, we are not required to provide an auditor attestation report on internal control over financial reporting, nor did we engage our independent registered public accounting firm to perform an audit of our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Plan and Non-Rule 10b5-1 Trading Arrangement Adoptions, Terminations, and Modifications

During the three months ended December 31, 2025, none of our directors or "officers" (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) and Item 408(c) of SEC Regulation S-K, respectively.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name, age and position of each of our directors and executive officers as of March 2, 2026. Our Board of Directors is currently comprised of six members. Our Board is divided into three classes of directors, each serving a staggered three-year term. At each annual meeting of stockholders, a class of directors is elected for a three-year term to succeed the class whose term is then expiring. Executive officers serve at the discretion of the Board of Directors and are appointed by the Board of Directors.

Name	Age	Position	Class of Director
Venkat Nelabhotla	65	President, Chief Executive Officer and Director	II
Robert Dickey IV	70	Interim Chief Financial Officer	-
Krishna K. Gupta	39	Chairman of the Board and Director	I
Stash Pomichter	26	Director	I
Shiladitya Sengupta	54	Director	I
John Tincoff	39	Director	II
Mohanjit Jolly	56	Director	III

The principal occupations and business experience for the past five years (and, in some instances, for prior years) of each of our directors and executive officers are as follows:

Venkat Nelabhotla, age 65, has served as a member of our Board of Directors and as our Chief Executive Officer since August 2025. He is the co-founder of and was the Chief Executive Officer and a member of the board of VTI since August 2017. Previously, he was co-founder and Chief Executive Officer of Vyome Biosciences Private Limited from August 2013. Mr. Nelabhotla is a seasoned senior executive with over 35 years of success across the pharmaceuticals, biotech, and consumer products industries. He brings a wealth of experience in driving corporate growth, innovation, global expansion, and organizational scaling. Mr. Nelabhotla has held key leadership roles at companies including Vyome Therapeutics Inc ("VTI"), Vyome Biosciences Private Limited, Emami Ltd., Aurobindo Pharma, Shantha Biotechnics (a Sanofi company), and CavinKare, where he has created significant value growth. As co-founder and chief executive officer of VTI, Mr. Nelabhotla has built a unique pipeline of products, secured significant funding for the Company's growth, and led the transaction to take Vyome Therapeutics public on Nasdaq through a reverse merger with concurrent financing. Before co-founding VTI, Mr. Nelabhotla served as co-founder and chief executive officer of Vyome Biosciences Private Limited, where he raised early stages of funding and advanced product pipeline development and commercialization of certain products. Mr. Nelabhotla served as chief executive officer and executive director of Emami Limited (EMAMILTD.NS) from June 2007 to September 2010, a publicly listed company, playing a pivotal role in significantly increasing the company's market capitalization through all-around organizational growth, including M&A. Mr. Nelabhotla also served as senior vice president at Aurobindo Pharma (AUROPHARMA.NS) from June 2005 to June 2007, contributing to significant revenue growth, and served as a senior executive at Shantha Biotechnics Private Limited (a Sanofi company) from June 2002 to June 2005, where he successfully launched biosimilar products and worked on developing a vaccine portfolio strategy. Mr. Nelabhotla also served as president of CavinKare Private Limited from September 1994 to June 2000; during his tenure, the company experienced a manyfold increase in revenues and multiple brand launches.

Robert Dickey IV, age 70, has served as our Interim Chief Financial Officer since August 2025. He has over 25 years of experience as a CFO as well as in other C-level and Board positions in both private and publicly-traded life sciences and medical device companies. Mr. Dickey is experienced in all stages of the corporate lifecycle, including start-up, fundraising, going public, high growth, turnarounds and exit strategies. Earlier in his career, Mr. Dickey spent 18 years in investment banking, mostly at Lehman Brothers, with a background split between M&A and capital markets transactions. His expertise includes public and private financings, M&A, partnering/licensing transactions, project management, overseeing company's finance and accounting functions, as well as interactions with Boards, VCs, shareholders and Wall Street. Mr. Dickey is the Founder and Managing Director at Foresite Advisors since 2020, which provides finance support and strategy for life science companies, including strategic CFO advisory, financial analysis and transactional support for fundraising and M&A. Mr. Dickey is also part of the Leadership Team at Cell One Partners since 2018, which provides consulting for cell and gene therapy companies. He currently serves as a member of the board of directors at AngioGenex, SFA Therapeutics and GSNO Therapeutics. Mr. Dickey holds an MBA from The Wharton School, University of Pennsylvania, and an AB from Princeton University. Mr. Dickey's prior experiences as a CFO and board positions in both private and publicly-traded life sciences and medical device companies qualify him to serve as the Chief Financial Officer of the Company.

Krishna K. Gupta, age 38, has served as a member and Chairman of our Board of Directors since August 2025. He is the founder and CEO of REMUS Capital, a technology-focused venture capital firm he initially founded in 2008. Mr. Gupta serves as a director on the boards of several privately held companies, including: Ceres AI, which provides Vision AI in agriculture; Spotta, which develops smart insect and pest monitoring solutions; and ZeroCater, which provides catering technology for enterprises. He is a co-founder and Chairman of Presto Phoenix, a market leader in conversational AI for restaurant drive-thrus, the first investor in Ginger, which was a leader in conversational AI for mental health and merged with Headspace, and the lead Series A investor in EquipmentShare, a leader in technology-enabled equipment rental for construction. Mr. Gupta has also served as a member of the board of directors of Allurion Technologies (NYSE: ALUR) since 2015. Prior to REMUS Capital, Mr. Gupta held roles at McKinsey & Company, a management consulting firm, and JPMorgan, an investment banking firm, where he advised several Fortune 100 clients on tech M&A deals. Mr. Gupta holds B.S. degrees in materials science and engineering, as well as in management sciences, both from the Massachusetts Institute of Technology. Mr. Gupta's prior experience in investing in technology and healthcare businesses, and public company experience, qualify him to serve as Chairman of our Board.

Stash Pomichter, age 26, has served as a member of our Board of Directors since August 2025. Mr. Pomichter has engineering, operating, and investing experience. Mr. Pomichter is a venture partner at REMUS Capital. He has also served as a co-founder and board director at Oculo Inc. and Mach Industries Inc., and board observer roles at companies including Allurion Technologies (NYSE: ALUR) and Presto Automation. As a technical founder, Mr. Pomichter has operated across healthcare, defense, and other contrarian verticals, starting companies that have gone onto raise more than $100m in venture capital funding. Mr. Pomichter has applied a hands-on approach to company building and his primary focus areas are AI applications in healthcare and other frontier industries. Mr. Pomichter attended the Massachusetts Institute of Technology where he studied Electrical Engineering & Computer Science before dropping out to pursue entrepreneurship and investing ventures, and has spent the last nine years building primarily science-backed MIT spinouts.

Shiladitya Sengupta, Ph.D., age 54, has served as a member of our Board of Directors since August 2025. He is a Co-founder of Vyome Therapeutics, Inc., our operational subsidiary ("VTI"). He is a founder and board member of Vyome Biosciences Private Limited since 2011. Dr. Sengupta is an associate professor of medicine at the Harvard Medical School since 2019, a principal investigator at the Dana Farber Cancer Institute since 2006, faculty member at the Health Science and Technology program at the Massachusetts Institute of Technology since 2005, and the director of Center for Engineered Therapeutics at the Brigham and Women's Hospital since 2018. His research group develops and applies nanotechnology and bioengineering tools for studying disease pathology, and designs novel drugs based on the understanding of the disease pathology. Dr. Sengupta is a co-founder and a member of the board of directors of Alyssum Therapeutics (venture backed) since 2019, a co-founder of Cerulean Pharmaceuticals (listed on NASDAQ), the founder and board member of India Innovation Research Center since 2011and was a founding director of Famygen Inc, (acquired by Viatris). Several of his research works have been translated to the clinics and have been commercialized. His honors include the Era of Hope Scholar award from the U.S. Department of Defense, the TR35 Top 35 Innovator from MIT Technology Review, TED Fellow, and Fellow of the Cambridge Commonwealth Society, and the Shakuntala Amir Chand Prize from Indian Council of Medical Research. Dr. Sengupta obtained his undergraduate education at the All India Institute of Medical Sciences, receiving a BS and MS. in medical pharmacology, where he received the Geeta Mital Gold Medal for best research in oncology. He then received a Ph.D. in pharmacology from Trinity College, University of Cambridge, where he was a Nehru Scholar and a Chevening Scholar. He completed his fellowship in biological engineering from Massachusetts Institute of Technology, and joined the faculty at Harvard in 2005. Dr. Sengupta has published over 100 papers, including in top journals such as Nature and Cell.

John Tincoff, age 39, has served as a member of our Board of Directors since August 2025. He has been a Partner at REMUS Capital since 2019. Mr. Tincoff co-manages the firm and leads its industrial AI investing practice, while also working on early-stage investments across companies spanning verticals including healthcare, energy, retail, agriculture, pharma, and manufacturing. In addition, he has served as a board member for five Remus portfolio companies where he led investments and was a board observer to over half a dozen more. He has considerable experience in governance and continues to serve as a mentor to young technology startups at incubators and university labs, including at the MIT Climate & Energy Prize. Prior to investing, Mr. Tincoff worked at a sister firm of REMUS Capital that provided strategic advisory services to venture-backed tech companies. As a partner there, he worked with founders, CEOs, and boards by advising on M&A, capital raising, strategic partnerships, and growth initiatives for a suite of early and growth-stage startups. John started his career working in energy & industrials investment banking. He earned a B.S. in Political Economy from Georgetown University's Walsh School of Foreign Service.

Mohanjit Jolly, age 56, has served as a member of our Board of Directors since August 2025. He has also served as a member of the Board of Vyome Therapeutics, Inc. since January 2019. Mr. Jolly has been working with and investing in technology startups in the US and India for over 20 years. He is one of the few venture capitalists who has been actively on the ground as a partner in both India and Silicon Valley. In January 2016, Mr. Jolly co-founded, and is a Partner at Iron Pillar, a tech growth firm investing in the US-India corridor. Mr. Jolly has led Iron Pillar's investments in Jiffy (AI For Wealth Management), Uniphore (Business AI Platform), Ushur (AI led Customer Experience Automation), Freehand (AI for Logistics), CoreStack (AI led Cloud Governance), Fold Health (AI enabled tech stack for value based care) and Sibros (Automotive communication platform). Before co-founding Iron Pillar in 2016, Mr. Jolly served as Partner and Managing Director at Draper Fisher Jurvetson (DFJ) for 9 years, establishing their India operations, overseeing their India venture portfolio and coordinating business development efforts with Fortune 500 companies for DFJ's global portfolio. Prior to this, Mr. Jolly was a Partner at Garage Technology Ventures, a Silicon Valley seed stage VC firm. During his early years in California, Mr. Jolly helped launch ViaSpace, a technology incubator in conjunction with Caltech and JPL, and Intel Play, a joint venture between Mattel and Intel. He also worked at Itek Optical Systems, a Boston based manufacturer of high-resolution reconnaissance systems. Mr. Jolly serves on the non-profit Board of The Unreasonable Group. Mr. Jolly earned his MBA from The Anderson School at UCLA and a B.S. and M.S. in Aeronautics and Astronautics from The Massachusetts Institute of Technology (MIT).

Composition of Our Board of Directors

Our Board of Directors consists of six members, each of whom are members pursuant to the board composition provisions of our certificate of incorporation.

On August 15, 2025, we amended our certificate of incorporation in accordance with our obligation under the Merger Agreement to appoint directors designated by certain persons and entities on our Board of Directors. Accordingly, the Board of Directors of the Company shall, unless determined otherwise by resolution duly adopted from time to time by the Board of Directors or pursuant to an agreement among stockholders, consist of: (a) two (2) directors to be designated by KKG Enterprises, LLC, including the Chairman of the Board of Directors (initially Krishna K. Gupta (as Chairman of the Board) and Stash Pomichter); (b) two (2) directors to be designated by Shiladitya Sengupta (initially Shiladitya Sengupta and Mohanjit Jolly); (c) the Chief Executive Officer, who shall be designated by Vyome Therapeutics, Inc., (initially Venkateswarlu Nelabhotla); and (d) one (1) non-employee director (initially John Tincoff). The certificate of amendment to our certificate of incorporation also specifies that the director designation rights of KKG Enterprises, LLC and Shiladitya Sengupta shall at all times be proportionate to the voting power held by each of KKG Enterprises, LLC and Shiladitya Sengupta, as a percentage of the overall votes entitled to be cast in the election of directors, in compliance with the applicable listing rules of the exchange on which the Company's stock is listed for trading.

Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Election of Officers and Family Relationships

Our executive officers are appointed by, and serve at the discretion of, our Board of Directors. There are no family relationships among any of our directors or executive officers.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our code of business conduct and ethics is available on the investor relations page of our corporate website *https://vyometx.com/investors/investor-home*. We intend to post any amendments to our code of business conduct and ethics, or any waivers thereto, on our corporate website, or in filings under the Exchange Act.

Director Independence

Our Board of Directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise or impair such director's ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our Board of Directors has determined that each of Krishna K. Gupta, Mohanjit Jolly, Stash Pomichter and John Tincoff, are "independent directors" as defined under the applicable rules and regulations of the Securities and Exchange Commission, or SEC, and the listing requirements and rules of Nasdaq.

Committees of the Board of Directors

Our Board of Directors has established an audit committee, a compensation committee and a nominating and governance committee, each of which have the composition and responsibilities described below. Members serve on these committees until their resignation or as otherwise determined by our Board of Directors.

Audit Committee

The members of our audit committee are Mohanjit Jolly (Chair), Krishna K. Gupta and John Tincoff. Our Board of Directors has determined that each of these persons satisfies the requirements for independence and financial literacy under the rules and regulations of Nasdaq and the SEC. Our Board of Directors has also determined that Mohanjit Jolly qualifies as an "audit committee financial expert," as defined in the SEC rules, and satisfies the financial sophistication requirements of Nasdaq. The audit committee will be responsible for, among other things:

- appointing, overseeing, and if need be, terminating any independent registered public accounting firm;
- assessing the qualification, performance and independence of our independent registered public accounting firm;
- reviewing the audit plan and pre-approving all audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing our financial statements and related disclosures;
- reviewing the adequacy and effectiveness of our accounting and financial reporting processes, systems of internal control and disclosure controls and procedures;
- reviewing our overall risk management framework;
- overseeing procedures for the treatment of complaints on accounting, internal accounting controls, or audit matters;
- reviewing and discussing with management and the independent auditor the results of our annual audit, reviews of our quarterly financial statements and our publicly filed reports;
- reviewing and approving related person transactions; and
- preparing the audit committee report that the SEC requires in our annual proxy statement.

Our audit committee operates under a written charter, adopted by our Board of Directors, which satisfies the applicable rules and regulations of the SEC and the applicable listing standards of Nasdaq. Prior to August 15, 2025, Gary Blackford, Lori McDougal and Arda Minocherhomjee served on the Audit Committee. The Audit Committee held 6 meetings in 2025. 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.

Compensation Committee

The members of our compensation committee are Mohanjit Jolly (Chair), Krishna K. Gupta and John Tincoff. Our Board of Directors has determined that each of these non-employee directors meets the requirements for independence under the rules of Nasdaq and the SEC. The compensation committee will be responsible for, among other things:

- reviewing the elements and amount of total compensation for executive officers;

- formulating and recommending any proposed changes in the compensation of our Chief Executive Officer for approval by the board;
- reviewing and approving any changes in the compensation for officers, other than our Chief Executive Officer;
- administering our equity compensation plans;
- reviewing annually our overall compensation philosophy and objectives, including compensation program objectives, target pay positioning and equity compensation; and
- preparing the compensation committee report that the SEC will require in our annual proxy statement.

Our compensation committee operates under a written charter, adopted by our Board of Directors, which satisfies the applicable rules and regulations of the SEC and the applicable listing standards of Nasdaq. The Compensation Committee held 1 meeting in 2025. During each of the meetings, the Compensation Committee held an executive session without members of management present.

Nominating and Governance Committee

The members of our nominating and governance committee are Krishna K. Gupta (Chair), Mohanjit Jolly and Stash Pomichter. Our Board of Directors has determined that each of these non-employee directors meets the requirements for independence under the rules of Nasdaq for service on this committee. The nominating and governance committee will be responsible for, among other things:

- evaluating and making recommendations regarding the composition, organization and governance of our Board of Directors and its committees,
- identifying, recruiting and nominating director candidates to the board if and when necessary;
- evaluating and making recommendations regarding the creation of additional committees or the change in mandate or dissolution of committees;
- reviewing and making recommendations with regard to our corporate governance guidelines and compliance with laws and regulations; and
- reviewing and approving conflicts of interest of our directors and corporate officers, other than related person transactions reviewed by the audit committee.

Our nominating and governance committee operates under a written charter adopted by our Board of Directors, which satisfies the applicable listing standards of Nasdaq. The Nominating and Corporate Governance Committee did not hold any meetings in 2025.

AI Committee

In addition to the above, the Company also has an Artificial Intelligence (AI) Committee of the Board. The AI Committee comprises Krishna K. Gupta, Mohanjit Jolly, and Stash Pomichter as members, all of which have deep AI expertise in artificial intelligence. The AI Committee is responsible for, among other things:

- Evaluating AI opportunities in healthcare, biotech, and medtech;
- Reviewing and prioritizing AI-driven healthcare projects;
- Overseeing data strategy, quality, and governance for AI initiatives;
- Ensuring compliance with healthcare and AI regulations;
- Monitoring AI technology trends and competitor activity;
- Assessing potential AI partnerships, investments, collaborations, and acquisitions;

- Tracking return on investment and performance metrics of AI projects;
- Advising the board on AI-related risks and mitigation strategies; and
- Promoting internal AI adoption and talent development across the Company.

Meetings of our Board of Directors and Committees

The Board of Directors held 12 meetings in 2025. Each director attended 75% or more of the aggregate of meetings of our Board of Directors and the committees of our board on which such director served.

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.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who beneficially own more than ten percent of our common stock to file with the SEC reports showing ownership of and changes in ownership of our common stock and other equity securities. Based on a review of reports filed by these reporting persons, we believe that the only late reports in the financial year ended December 31, 2025 were a Form 3 and Form 4 filed on September 11, 2025 by Robert Dickey reporting his appointment as Interim Chief Financial Officer and a transaction on August 15, 2025, respectively, a Form 3 filed on September 11, 2025 and a Form 4 filed on September 22, 2025 by Venkat Nelabhotla reporting his appointment as President and Chief Executive Officer and a transaction on August 15, 2025, respectively, a Form 3 filed on September 18, 2025 by John Tincoff reporting his appointment as a member of our Board of Directors on August 15, 2025, a Form 3 filed on November 17, 2025 by Shiladitya Sengupta reporting his appointment as a member of our Board of Directors on August 15, 2025, a Form 3 filed on November 18, 2025 by Mohanjit Jolly reporting his appointment as a member of our Board of Directors on August 15, 2025, and a Form 3 filed on November 19, 2025 by Stash Pomichter reporting his appointment as a member of our Board of Directors on August 15, 2025. In addition, Krishna Gupta failed to file a Form 3 and a Form 4 reporting his appointment as a member of our Board of Directors and a transaction on August 15, 2025, respectively.

Involvement in Certain Legal Proceedings

Our directors and executive officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;
4. being found by a court of competent jurisdiction in a civil action, the SEC or the Commodity Futures Trading Commission to have violated a Federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
5. being subject of, or a party to, any Federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any Federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
6. being subject of or party to any sanction or order, not subsequently reversed, suspended, or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Insider Trading Policy

The Company has adopted an insider trading policy governing the purchase, sale, and/or other disposition of its securities by its directors, officers, employees and independent contractors that the Company believes is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to the Company.

Directors, executive officers, employees and other related persons may not buy, sell or engage in other transactions in the Company's shares while aware of material non-public information; buy or sell securities of other companies while aware of material non-public information about those companies that they became aware of as a result of business dealings between the Company and those companies; or disclose material non-public information to any unauthorized persons outside of the Company. The policy also restricts trading and other transactions for a limited group of Company employees (including executives and directors) to defined window periods that follow the Company's quarterly earnings releases. In addition, it is the Company's intent to comply with applicable laws and regulations relating to insider trading.

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.

ITEM 11. 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, 2025 and 2024.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Non-equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Venkat Nelabhotla[(1)] *President and Chief Executive Officer*	2025	260,000	-	208,302	-	10,409	478,711
Robert Dickey IV[(2)] *Interim Chief Financial Officer*	2025	81,638	-	19,160	-	-	100,798
Paul F. Hickey[(3)] *Former President and Chief Executive Officer*	2025	200,000	60,733			600,000[(5)]	860,733
		323,984	80,000	-	-	-	403,984
Thomas Stankovich[(4)] *Former Chief Financial Officer*	2025	96,009	10,000				106,099
	2024	148,698	-	-	-	-	148,698

(1) Venkat Nelabhotla was appointed as the President and Chief Executive Officer of the Company effective upon the consummation of the Merger on August 15, 2025.
(2) Robert Dickey IV was appointed as the Interim Chief Financial Officer of the Company effective upon the consummation of the Merger on August 15, 2025.

(3) Paul F. Hickey resigned as the President and Chief Executive Officer of the Company effective upon the consummation of the Merger on August 15, 2025.
(4) Thomas Stankovich resigned as the Chief Financial Officer of the Company effective upon the consummation of the Merger on August 15, 2025.
(5) In the event Mr. Hickey's employment is terminated by the Company without cause or Mr. Hickey resigns for good reasons, he will be entitled to receive a severance payment.

Venkat Nelabhotla

On September 30, 2019, Vyome Therapeutics, Inc. ("VTI") and Mr. Nelabhotla entered into an employment agreement appointing Mr. Nelabhotla as the President and Chief Executive Officer of VTI. Pursuant to this agreement, Mr. Nelabhotla is entitled to a base salary of $260,000 per annum. The employment agreement also provides for an annual bonus of up to $133,572 contingent upon the achievement by VTI of any or all of the milestones described in the employment agreement. Both VTI and Mr. Nelabhotla can terminate the employment agreement for any reason or no reason (including, without limitation, for convenience, cause (as defined in the employment agreement) or good reason (as defined in the employment agreement).

In addition, Mr. Nelabhotla is entitled to severance payments under the employment agreement. Upon termination of the agreement by either party, VTI shall pay upon due adjustments or provide to Mr. Nelabhotla (or to his authorized representative or estate) any earned but unpaid base salary, annual bonus earned and payable but not yet paid, unpaid expense reimbursements and accrued but unused vacation on or before the time required by law but in no event more than 30 days after date of such termination. In the event the employment agreement is terminated without cause (as defined in the employment agreement) or by Mr. Nelabhotla for good reason, Mr. Nelabhotla shall be entitled to, among others, an amount equal to the sum of: (i) 75% of his base salary (as defined in the employment agreement); and (ii) 75% of his target bonus compensation (as defined in the employment agreement) for the then current fiscal year. In addition, subject to Mr. Nelabhotla's continuous service to VTI from the date of the employment agreement through the closing of a change of control (as such term is defined in the VTI's 2018 equity incentive plan) (or, in the event of any termination by VTI of the employment agreement pursuant to the employment agreement without cause at any time after VTI enters into a definitive agreement with respect to a change of control transaction and thereafter the closing of such change of control transaction is consummated), each outstanding stock option or other equity award in VTI held by Mr. Nelabhotla immediately prior to such closing that has not otherwise previously become vested shall automatically become fully vested immediately prior to such closing and, if applicable, shall automatically become exercisable immediately prior to such closing and, if applicable, shall automatically become exercisable immediately prior to such closing for one hundred percent (100%) of the shares of equity of VTI subject thereto.

Pursuant to the consummation of the Merger, Mr. Nelabhotla has been serving as the President and Chief Executive Officer of the Company under the terms of the aforementioned agreement between him and VTI until such time as the Board of Directors determines to enter into a new employment agreement.

Robert Dickey

On August 4, 2025, the Company entered into an agreement for the appointment of Robert Dickey as its full time Interim Chief Financial Officer. Pursuant to this agreement, Mr. Dickey is entitled to a payment of up to $15,000 per calendar month, prorated for partial months. The agreement can be terminated by either party for reasons, including, among others, cause (as defined in the agreement), upon fifteen (15) days prior written notice to the other party, without cause upon thirty (30) days prior written notice to the other party. The agreement does not provide for the payment of severance upon termination.

Long-Term Incentives

Our long-term equity incentive plans allow 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.

On October 27, 2025, the stockholders of the Company approved the adoption of the 2025 Equity Incentive Plan, which was adopted by the Board of Directors on October 2, 2025 and replaced the prior 2022 Equity Incentive Plan. Under the 2025 Equity Incentive Plan, 2,000,000 shares of our common stock are available for issuance pursuant to future grants or awards.

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, 2025.

Outstanding Equity Awards

	Option Awards					Stock Awards			
Name	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)**	**Option exercise price ($)**	**Option expiration date**	**Number of shares or units of stock that have not vested (#)**	**Market value of shares of units of stock that have not vested ($)**	**Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)**	**Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)**
Venkat Nelabhotla(1) *President and Chief Executive Officer*	985,184 109 75	N/A	N/A	0.41 2,400 4,500	7/31/35 12/21/28 12/21/28	N/A	N/A	N/A	N/A
Robert Dickey IV(2) *Interim Chief Financial Officer*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paul F. Hickey(3) *Former President and Chief Executive Officer*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Thomas Stankovich(4) *Former Chief Financial Officer*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

(1) Venkat Nelabhotla was appointed as the President and Chief Executive Officer of the Company effective upon the consummation of the Merger on August 15, 2025.
(2) Robert Dickey IV was appointed as the Interim Chief Financial Officer of the Company effective upon the consummation of the Merger on August 15, 2025.

(3) Paul F. Hickey resigned as the President and Chief Executive Officer of the Company effective upon the consummation of the Merger on August 15, 2025.
(4) Thomas Stankovich resigned as the Chief Financial Officer of the Company effective upon the consummation of the Merger on August 15, 2025.

Director Compensation

For 2025, each non-employee director received no compensation for serving on the Board.

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. Nelabhotla is the only director who is also an employee of the Company.

The following table shows the compensation of the non-employee members of our Board of Directors during fiscal year 2025:

Director Compensation in 2025

Name[(1)]	Fees Earned or Paid in Cash ($)[(2)]
Krishna K. Gupta*	Nil
Stash Pomichter*	Nil
Shiladitya Sengupta*	Nil
John Tincoff*	Nil
Mohanjit Jolly*	Nil
Dan Gladney*	Nil
Gary Blackford[(3)]	Nil
Lori McDougal*	Nil
Arda Minocherhomjee*	Nil

(1) Venkat Nelabhotla, our President and Chief Executive Officer, and Paul Hickey, our former President and Chief Executive Officer (who resigned effective upon consummation of the Merger) are not included in this table because they were each an employee of the Company during 2025 and thus received no compensation for their services as a director. The compensation that Mr. Nelabhotla and Mr. Hickey received as employees 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 2025 described above under the heading "*Director Compensation*."
(3) Gary Blackford resigned from the Board of Directors and all related committees effective March 15, 2025.
* In connection with the consummation of the Merger and pursuant to the Merger Agreement, on August 15, 2025, the Board elected and designated Krishna Gupta, Stash Pomichter, Shiladitya Sengupta, John Tincoff and Mohanjit Jolly to the Board of Directors effective immediately. Dan Gladney, Lori McDougal and Arda Minocherhomjee resigned as directors of the Company effective upon the consummation of the Merger.

Actions to Recover Erroneously Awarded Compensation

At no time during the last fiscal year was the Company required to prepare an accounting restatement that required recovery of an erroneously awarded compensation pursuant to our Clawback Policy.

Policies and Practices related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information ("MNPI")

The Company has a strict policy of not issuing options or allowing its insiders to conduct stock trades at times, subject to any allowable trades that might occur pursuant to a 10b5-1 Trading Plan, where MNPI is known or a material transaction is anticipated to occur. Each insider and employee of the Company is required to read and sign the Company's Insider Trading Policy, which prescribes certain set periods that prohibit insider trading. Other than as established for black-out periods associated with our quarterly and annual financial statement filings, our executive management will also issue notices of black-out trading periods if they are aware of material transactions which they anticipate closing.

The timing of equity award grants is determined with consideration to a variety of factors, including but not limited to, the achievement of pre-established performance targets, market conditions and internal milestones. The Company does not follow a predetermined schedule for the granting of equity awards; instead, each grant is considered on a case-by-case basis to align with the Company's strategic objectives and to ensure the competitiveness of our compensation packages.

In determining the timing and terms of an equity award, the Board or the Compensation Committee may consider MNPI to ensure that such grants are made in compliance with applicable laws and regulations. The Board's or the Compensation Committee's procedures to prevent the improper use of MNPI in connection with the granting of equity awards include oversight by legal counsel and, where appropriate, delaying the grant of equity awards until the public disclosure of such MNPI.

The Company is committed to maintaining transparency in its executive compensation practices and to making equity awards in a manner that is not influenced by the timing of the disclosure of MNPI for the purpose of affecting the value of executive compensation. The Company regularly reviews its policies and practices related to equity awards to ensure they meet the evolving standards of corporate governance and continue to serve the best interests of the Company and its stockholders.

In the year ended December 31, 2025, no options were granted to our named executive officers within four business days prior to, or one business day following, the filing or furnishing of a periodic or current report by us that disclosed MNPI.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information with respect to the beneficial ownership of our shares as of March 2, 2026 by (i) each person or entity known by us to own beneficially more than 5% of our outstanding shares; (ii) each of our directors and executive officers individually; and (iii) all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the applicable rules and regulations of the SEC and includes voting or investment power with respect to our capital stock. Under such rules, beneficial ownership includes any shares over which the individual has the sole or shared voting power or investment power and any shares that the individual has the right to acquire within 60 days of March 2, 2026, through the exercise of stock options, warrants or other convertible securities or any other right. Shares of our common stock that a person has the right to acquire within 60 days of March 2, 2026 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights but are not deemed outstanding for purposes of computing the percentage ownership of any other person (except with respect to the percentage ownership of all directors and executive officers as a group). All of our shareholders, including the shareholders listed below, have the same voting rights attached to their shares of common stock. Unless otherwise noted below, each director's, officer's and shareholder's address is care of Vyome Holdings, Inc., One Mifflin Place, Suite 400, Cambridge, MA 02138.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficial Ownership
5% Stockholders (Other than Directors and Executive Officers)		
Iron Pillar Fund I Ltd.[1]	454,456	6.48%
Navam Capital Private Limited[2]	721,283	10.28%
MNI Ventures[3]	1,001,518	14.26%
Hunter Ventures Limited[4]	409,431	5.83%
Man Kwon Lam[5]	391,526	5.58%
Felix Kar Chung Lee[6]	391,526	5.58%
Directors and Executive Officers		
Krishna Gupta[7]	586,068	8.28%
Venkat Nelabhotla[8]	615,236	8.06%
Mohanjit Jolly[9]	454,456	6.48%
Shiladitya Sengupta[10]	624,520	8.17%
Stash Pomichter[11]	17,832	*
John Tincoff[12]	17,832	*
Rob Dickey[13]	762	*
All directors and executive officers as a group (7 persons)	2,316,706	33.00%

* Less than 1%

(1) Shareholding consists of 454,456 shares of common stock held by Iron Pillar Fund I Ltd.

(2) Shareholding consists of 721,283 entitled shares of common stock held by Navam Capital Private Limited (all of which are subject to the put-call option agreements using its shares in Vyome Therapeutics, Inc. and Vyome Therapeutics Limited).

(3) Shareholding consists of 1,001,518 shares of common stock held.

(4) Shareholding consists of 409,431 shares of common stock held.

(5) Shareholding consists of 391,526 shares of common stock held.

(6) Shareholding consists of 391,526 shares of common stock held.

(7) Consists of 6,232 shares of common stock held by Romulus Vyome Special Opportunity LP, 1,706 shares of common stock held by Romulus Vyome Special Opportunity III, LLC, 328,474 shares of common stock held by KKG Enterprises LLC and 249,456 of fully vested stock options. Krishna Gupta is the managing partner of Romulus Vyome Special Opportunity LP and Romulus Vyome Special Opportunity III, LLC. Romulus Vyome Special Opportunity LP and Romulus Vyome Special Opportunity III, LLC are affiliates.

(8) Consists of 8 shares of common stock and 615,228 of fully vested stock options.

(9) Consists of 454,456 shares of common stock held by Iron Pillar Fund I Ltd. Mohanjit Jolly is a general partner of Iron Pillar Fund I Ltd. Mohanjit Jolly is a general partner of Iron Pillar Fund I Ltd. and an advisor to and representative of Iron Pillar India Fund I for investments in Vyome.

(10) Consists of 92 shares of common stock and 624,428 of fully vested stock options.

(11) Consists of 17,832 fully vested stock options.

(12) Consists of 17,832 fully vested stock options.

(13) Consists of 762 shares of common stock.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes the equity compensation plans under which our securities may be issued as of December 31, 2025 and does not include grants made or cancelled and options exercised after such date.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by security holders	Nil	$ Nil	2,000,000
Equity compensation plans not approved by security holders	Nil	$ Nil	Nil
Total	Nil	$ Nil	2,000,000

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

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.

Except as set forth below, there were no transactions since the beginning of the fiscal year beginning January 1, 2024, or any currently proposed transactions, in which the Company was or is to be a participant and the amount involved exceeds $120,000, and in which any related person had or will have a direct or indirect material interest.

- On January 1, 2019, Dr. Shiladitya Sengupta, a member of our Board of Directors, entered into a consulting agreement and an addendum (together, "Consulting Agreement") with Vyome Therapeutics, Inc. ("VTI") to provide certain consulting services to VTI. Under the Consulting Agreement, Dr. Sengupta is entitled to a fee of $100,000 per annum payable in four equal instalments every quarter. Both VTI and Dr. Sengupta can terminate the Consulting Agreement for any reason or no reason (including, without limitation, for convenience or cause (as defined in the Consulting Agreement) upon giving of 30 days prior written notice of such termination. Dr. Sengupta has been acting as a consultant to the Company under the terms of the aforementioned agreement between him and VTI until such time as the board of directors of the Company determines to enter into a new agreement. In addition, Dr. Sengupta also received stock awards of VTI with an estimated fair value of $151,939 in the financial year ended December 31, 2024.

Director Independence

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise or impair such director's ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors has determined that each of Krishna K. Gupta, Mohanjit Jolly, Stash Pomichter and John Tincoff, are "independent directors" as defined under the applicable rules and regulations of the Securities and Exchange Commission, or SEC, and the listing requirements and rules of Nasdaq.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table represents aggregate fees billed to the Company for the fiscal year ended December 31, 2025 and December 31, 2024 by Haskell & White LLP, RSM US LLP and Kreit & Chiu CPA LLP, the Company's independent registered accounting firms during such fiscal years.

	Years Ended December 31,	
	2025	**2024**
Audit fees[(1)]	$ 537,000	$ 840,000
Audit-related fees[(2)]	761,000	331,000
Total	$ 1,298,000	$ 1,171,000

(1) Includes fees billed, or estimates of fees to be billed, for professional services rendered in connection with the audit of our consolidated financial statements for the referenced fiscal year ended, review of interim consolidated financial statements and services that are normally provided by Haskell & White LLP, RSM US LLP and Kreit & Chiu CPA LLP in connection with statutory and regulatory filings and engagements.

(2) Includes audit related fees billed, or estimates of fees to be billed, for professional services rendered in connection with the Company's planned merger and assets sale, reverse stock split, and other ad-hoc filings.

PART IV.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. Consolidated Financial Statements. See "*Index to Consolidated Financial Statements*" in Part II, Item 8 herein.

2. Financial Statement Schedules. Other schedules are not applicable and have not been included herein.

3. Exhibits.

Exhibit No.	Description
2.1	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 Securities and Exchange Commission on July 9, 2024).
2.2	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 Securities and Exchange Commission on July 9, 2024).
2.3	Amendment to Asset Purchase Agreement, dated April 25, 2025, between ReShape Lifesciences Inc. and Ninjour Health International Limited (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 28, 2025).
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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission on July 24, 2019).
3.4	Third Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 15, 2021).
3.5	Fourth Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 15, 2021).
3.6	Fifth Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 28, 2022).
3.7	Sixth Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2024).

3.8	Seventh Amendment to Restated Certificate of Incorporation, as amended, of the Company (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 9, 2025).
3.9	Eighth Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 19, 2025).
3.10	Ninth Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 19, 2025).
3.11	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 Securities and Exchange Commission on January 18, 2024).
3.12	Amended and Restated Certificate of Designation to Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 19, 2025).
3.13	Certificate of Merger merging Raider Lifesciences into Vyome Therapeutics, Inc. (incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 19, 2025).
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 by with the Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 by the Company on April 26, 2023).
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 by the Company 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 Securities and Exchange Commission on June 8, 2018).
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 Securities and Exchange Commission 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 Securities and Exchange Commission 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 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 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 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 herein by reference to Exhibit 4.31 to the Company's Registration Statement on Form S-1 filed on December 20, 2024 (File No. 333-283952)).
4.32	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.32 to Amendment No. 2 to Registration Statement on Form S-1 filed by ReShape Lifesciences Inc. on February 13, 2025 (File No. 333-284362)).
4.33	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 20, 2025).
4.34	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 12, 2025).
10.1†	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 Securities and Exchange Commission on May 25, 2018).
10.2†	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 Securities and Exchange Commission on November 14, 2017).

10.3†	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 Securities and Exchange Commission on December 20, 2022).
10.4	Form of Indemnification Agreement entered into by and between the Company 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 Securities and Exchange Commission on July 6, 2007.
10.5	Lease agreement, entered into January 20, 2017, by and between the Company 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 Securities and Exchange Commission on April 2, 2018).
10.6†	Executive Employment Agreement, dated October 29, 2019, by and between the Company and Thomas Stankovich (incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2024).
10.7	Employment Agreement dated September 30, 2019 between Vyome Therapeutics, Inc. and Venkateswarlu Nelabhotla (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on October 1, 2024).
10.8*	Development & Licensing Agreement dated December 15, 2020 between Vyome Therapeutics Limited and Sun Pharma Laboratories Limited (incorporated by reference to Exhibit 10.20 to Amendment No. 1 to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on December 6, 2024).
10.9	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 Securities and Exchange Commission on June 23, 2022).
10.10†	Retention Bonus Agreement, dated August 2, 2022, between the Company and Thomas Stankovich (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 2, 2022.
10.11	Lease Agreement dated October 1, 2022 between Neeta Jain and Vyome Therapeutics Limited for the property located at C-4/201, Akshar Pavillion, Vadodara - 390021, India (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on October 1, 2024).
10.12†	Employment Agreement, dated November 1, 2022, by and between ReShape and Paul F. Hickey (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 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 Securities and Exchange Commission 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 Securities and Exchange Commission on November 14, 2022).

10.15	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 Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 17, 2023).
10.16	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 Securities and Exchange Commission on April 26, 2023).
10.17	Lease Extension Letter dated September 5, 2023 between Neeta Jain and Vyome Therapeutics Limited for the property located at C-4/201, Akshar Pavillion, Vadodara - 390021, India (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on October 1, 2024).
10.18	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 Securities and Exchange Commission on September 22, 2023).
10.19	Lease Agreement dated January 1, 2024 between Sita Gupta and Vyome Therapeutics Limited for the property located at ground floor, Industrial Property no. 465, FIE, Patparganj, New Delhi - 110092 India (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on October 1, 2024).
10.20	Lease Agreement dated January 1, 2024 between Sita Gupta and Vyome Therapeutics Limited for the property located at basement floor, Industrial Property no. 465, FIE, Patparganj, New Delhi - 110092 India (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on October 1, 2024).
10.21**	Renewal Service Agreement dated February 7, 2026 between Regus Management Group, LLC and Vyome Therapeutics, Inc. for the property located at 100 Overlook Center, 2nd Floor, Princeton, New Jersey - 08540, United States.
10.22**	Office Service Agreement dated September 3, 2025 between Regus Management Group, LLC and Vyome Therapeutics, Inc. for the property located at Suite 400, 125 Cambridge Park Drive, Cambridge - 02140, United States.
10.23**	Renewal Service Agreement dated September 16, 2025 between Regus Management Group, LLC and Vyome Holdings, Inc. for the property located at Suite 400, 125 Cambridge Park Drive, Cambridge - 02140, United States.
10.24	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 Securities and Exchange Commission on July 9, 2024)
10.25	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 Securities and Exchange Commission on July 9, 2024)

10.26	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 Securities and Exchange Commission on July 9, 2024)
10.27	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 Securities and Exchange Commission on July 9, 2024)
10.28	Consulting Agreement dated August 26, 2024 between Vyome Therapeutics, Inc. and Foresite Advisors, LLC (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on October 1, 2024).
10.29	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 Securities and Exchange Commission on October 17, 2024).
10.30	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 Securities and Exchange Commission on October 17, 2024).
10.31	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 Securities and Exchange Commission on October 17, 2024).
10.32	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 Securities and Exchange Commission on October 17, 2024).
10.33	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 Securities and Exchange Commission on October 17, 2024).
10.34	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 Securities and Exchange Commission on October 17, 2024).
10.35	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 Securities and Exchange Commission on October 17, 2024).
10.36	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).
10.37	Form of Securities Purchase Agreement, by and between ReShape Lifesciences Inc. and the investors in the offering (incorporated by reference to Exhibit 10.27 to Amendment No. 2 to Registration Statement on Form S-1 filed by ReShape Lifesciences Inc. on February 13, 2025).

10.38	Form of Placement Agent Agreement by and between ReShape Lifesciences Inc. and the investors party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 12, 2025).
10.39	Promissory Note, dated April 15, 2025, between ReShape Lifesciences Inc. and Vyome Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 21, 2025).
10.40	Promissory Note, dated June 27, 2025, between ReShape Lifesciences Inc. and Vyome Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2025).
10.41†	Interim Full-Time Chief Financial Officer Consulting Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 19, 2025).
10.42	Amendment to Equity Distribution Agreement dated August 20, 2025, by and between the Company and Maxim Group LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 20, 2025).
10.43	Binding Letter of Intent, dated December 17, 2025, by and among Vyome Holdings, Inc., LiveChain, Inc., and Remus Capital Series B II, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 23, 2025).
10.44	Notes Purchase and Exchange Agreement, dated February 20, 2026, by and among Vyome Holdings, Inc., LiveChain, Inc., LICH AI, Inc., and Remus Capital Series B II, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2026).
10.45**	Amendment No. 1 to Notes Purchase and Exchange Agreement, dated February 25, 2026, by and among Vyome Holdings, Inc., LiveChain, Inc., LICH AI, Inc., and Remus Capital Series B II, L.P.
21.1**	List of Subsidiaries
23.1**	Consent of Independent Registered Public Accounting Firm
31.1**	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	Financial statements from the Annual Report on Form 10-K of the Company for the year ended December 31, 2025, formatted in Inline XBRL: (i) the Consolidated Statements of Operations, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Stockholders' Equity; (iv) the Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* The schedules and exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

** Filed herewith.

† Indicates management contract or compensation plan or agreement.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VYOME HOLDINGS, INC.

BY: */s/ Venkat Nelabhotla*
Venkat Nelabhotla
President and Chief Executive Officer
(principal executive officer)

BY: */s/ Robert Dickey IV*
Robert Dickey IV
Interim Chief Financial Officer
(principal financial and accounting officer)

Dated: March 18, 2026

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Venkat Nelabhotla, as his attorney-in-fact, with full power of substitution, for him in any and all capacities, to sign any and all amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or his substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Venkat Nelabhotla Venkat Nelabhotla	President and Chief Executive Officer (principal executive officer)	March 18, 2026
/s/ Robert Dickey IV Robert Dickey IV	Interim Chief Financial Officer (principal financial and accounting officer)	March 18, 2026
/s/ Krishna K. Gupta Krishna K. Gupta	Chairman of the Board and Director	March 18, 2026
/s/ Shiladitya Sengupta Shiladitya Sengupta	Director	March 18, 2026
/s/ Mohanjit Jolly Mohanjit Jolly	Director	March 18, 2026
/s/ Stash Pomichter Stash Pomichter	Director	March 18, 2026
/s/ John Tincoff *John Tincoff*	Director	March 18, 2026

RENEWAL SERVICE AGREEMENT

AGREEMENT DATE : FEBRUARY 7, 2026

BUSINESS CENTER ADDRESS:
Regus
NJ, Princeton - Overlook
100 Overlook Center
2nd Floor
Princeton
New Jersey
08540
United States of America

CLIENT ADDRESS (NOT ABUSINESS CENTER ADDRESS):	
Company Name	Vyome Therapeutics Inc.
Contact Name	Venkateswarlu Nelabhotla
Address *	100, Overlook center 2nd floor
City *	Princeton
State/ County/ Province/ Municipality/ Governorate *	New Jersey
Post Code *	08540
Country *	United States of America
Phone number *	United States of America +1 973-832-8147
Email *	nvenkat@vyometx.com

RENEWAL PAYMENT DETAILS (EXCLUDING TAX AND OPTIONAL SERVICES)

Office Number	Number of People	Total Monthly Office Price	Discount for Longer Term	Total Monthly Discount	Discounted Monthly Renewal Price
2132	1	$ 880.40	$ 66.10	$ 66.10	**$ 814.30**
TOTALS	**1**	**$ 880.40**	**$ 66.10**	**$ 66.10**	**$ 814.30**

SERVICE PROVISION:	Start Date	May 1, 2026	End Date*	July 31, 2026

COMMENTS:

* All agreements end on the last calendar day of the month. More info

- Invoices/Fees are charged on a monthly basis which is calculated based on a 30-day month. More info
- Arefundable service retainer equivalent to 2 x monthly office fee will be payable. More info

Promotion: Any promotion or discount is for the initial term of the agreement.

TERMS AND CONDITIONS

We are Regus Management Group, LLC, please click the link below for terms and conditions.

AGREEMENT TO ARBITRATE/CLASS ACTION WAIVER: YOU AND WE MUTUALLY AGREE TO WAIVE OUR RESPECTIVE RIGHTS TO RESOLVE DISPUTES IN A COURT OF LAW BY A JUDGE OR JURY AND AGREE TO RESOLVE ANY DISPUTE BETWEEN US BY BINDING ARBITRATION, except as expressly provided in this paragraph. Any dispute or claim relating in any way or arising out of this Agreement shall be resolved by binding arbitration administered by the American Arbitration Association in accord with its Commercial Arbitration Rules (available at www.adr.org), except that You or We may assert claims in small claims court and We may pursue a court action to remove You if You do not leave when this Agreement terminates (and You may pursue a court action to prevent Your removal). The arbitrator, and not a court of law, shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability, or formation of this agreement to arbitrate, and shall conduct the arbitration on an individual basis only and not as a class or representative action. You and We acknowledge that this Agreement is governed by the Federal Arbitration Act and will survive after this Agreement terminates or your relationship with Us ends.

CLASS ACTION WAIVER: YOU UNDERSTAND AND AGREE THAT YOU AND WE MAY EACH BRING CLAIMS AGAINST THE OTHER, WHETHER IN COURT OR ARBITRATION, ONLY IN AN INDIVIDUAL CAPACITY AND NOT ON A CLASS, COLLECTIVE ACTION, OR REPRESENTATIVE BASIS, AND EXPRESSLY WAIVE THE RIGHT TO PURSUE OR HAVE A DISPUTE RESOLVED AS A PLAINTIFF OR CLASS MEMBER IN ANY PURPORTED CLASS, COLLECTIVE OR REPRESENTATIVE PROCEEDING.

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CONFIRMATION NO : R-3651171

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IWG International Workplace Group

Regus · SPACES. · HQ · Signature by Regus · No 18

OFFICE SERVICE AGREEMENT

AGREEMENT DATE : SEPTEMBER 3, 2025

BUSINESS CENTER ADDRESS:
Regus
MA, Cambridge - Harvard Square-Mifflin Place
Harvard Square
One Mifflin Place
Suite 400
Cambridge
Massachusetts
02138
United States of America

CLIENT ADDRESS (NOT ABUSINESS CENTER ADDRESS):	
Company Name	Vyome Therapeutics Inc
Contact Name	Venkat Nelabhotla
Address *	100 Overlook Center 2nd floor
City *	Princeton
State/ County/ Province/ Municipality/ Governorate *	New Jersey
Post Code *	08540
Country *	United States of America
Phone number *	United States of America +1 973-832-8147
Email *	nvenkat@vyometx.com

OFFICE PAYMENT DETAILS (EXCLUDING TAX AND OPTIONAL SERVICES)

Office Number	Number of People	Total Monthly Office Price	Discount for Longer Term	Total Monthly Discount	Discounted Monthly Office Price
408ResCo-work04	1	$ 411.00	$ 32.00	$ 32.00	**$ 379.00**
TOTALS	**1**	**$ 411.00**	**$ 32.00**	**$ 32.00**	**$ 379.00**
				7.79%	

SERVICE PROVISION:	Start Date	October 1, 2025	End Date*	September 30, 2026

COMMENTS:

* All agreements end on the last calendar day of the month. More info

- Invoices/Fees are charged on a monthly basis which is calculated based on a 30-day month. More info
- An Activation fee of $ 65.00 per occupant will be payable. More info
- A refundable service retainer equivalent to 1 x monthly office fee will be payable. More info

Promotion: Any promotion or discount is for the initial term of the agreement.

TERMS AND CONDITIONS

We are Regus Management Group, LLC, referred to in the terms and conditions as “We”, “Us”, “Our”. The Company Name listed above will be referred to in the terms and conditions as “You”, “Your”. This Agreement incorporates Our terms of business set out on attached Terms and Conditions, attached House Rules and Service Price Guide (where available), which You confirm You have read and understood. We both agree to comply with those terms and our obligations as set out in them. This agreement is binding from the agreement date and may not be terminated once it is made, except in accordance with its terms. Note that the Agreement does not come to an end automatically. See “Automatic Renewal” section of Your terms and conditions for the notice terms if You wish to end your agreement.

AGREEMENT TO ARBITRATE/CLASS ACTION WAIVER: YOU AND WE MUTUALLY AGREE TO WAIVE OUR RESPECTIVE RIGHTS TO RESOLVE DISPUTES IN A COURT OF LAW BY A JUDGE OR JURY AND AGREE TO RESOLVE ANY DISPUTE BETWEEN US BY BINDING ARBITRATION, except as expressly provided in this paragraph. Any dispute or claim relating in any way or arising out of this Agreement shall be resolved by binding arbitration administered by the American Arbitration Association in accord with its Commercial Arbitration Rules (available at www.adr.org), except that You or We may assert claims in small claims court and We may pursue a court action to remove You if You do not leave when this Agreement terminates (and You may pursue a court action to prevent Your removal). The arbitrator, and not a court of law, shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability, or formation of this agreement to arbitrate, and shall conduct the arbitration on an individual basis only and not as a class or representative action. You and We acknowledge that this Agreement is governed by the Federal Arbitration Act and will survive after this Agreement terminates or your relationship with Us ends.

CLASS ACTION WAIVER: YOU UNDERSTAND AND AGREE THAT YOU AND WE MAY EACH BRING CLAIMS AGAINST THE OTHER, WHETHER IN COURT OR ARBITRATION, ONLY IN AN INDIVIDUAL CAPACITY AND NOT ON A CLASS, COLLECTIVE ACTION, OR REPRESENTATIVE BASIS, AND EXPRESSLY WAIVE THE RIGHT TO PURSUE OR HAVE A DISPUTE RESOLVED AS A PLAINTIFF OR CLASS MEMBER IN ANY PURPORTED CLASS, COLLECTIVE OR REPRESENTATIVE PROCEEDING.

☑ **I accept the terms and conditions / house rules**

Download the terms and conditions

Download the house rules

CONFIRM BY TYPING YOUR NAME IN THE BOX BELOW

Name : Venkat Nelabhotla on behalf of

Vyome Therapeutics Inc

Signed on
September 3, 2025

I confirm these details are correct to the best of my knowledge

This website is secure. Your personal details are protected at all times.

Print Agreement

CONFIRMATION NO : PRT12733503

IF YOU NEED ASSISTANCE CALL OUR HELPLINE ON +1-855-400-3575

RENEWAL SERVICE AGREEMENT

AGREEMENT DATE : SEPTEMBER 16, 2025

BUSINESS CENTER ADDRESS:
MA, Cambridge - Harvard Square-Mifflin Place
Harvard Square
One Mifflin Place
Suite 400
Cambridge
Massachusetts
02138
United States of America

CLIENT ADDRESS (NOT ABUSINESS CENTER ADDRESS):	
Company Name	Vyome Holdings, Inc.
Contact Name	Venkateswarlu Nelabhotla
Address *	100, Overlook center 2nd floor
City *	Princeton
State/ County/ Province/ Municipality/ Governorate *	New Jersey
Post Code *	08540
Country *	United States of America
Phone number *	United States of America +1 9738328147
Email *	nvenkat@vyometx.com

RENEWAL PAYMENT DETAILS (EXCLUDING TAX AND OPTIONAL SERVICES)

Office Number	Number of People	Total Monthly Office Price	Discount for Longer Term	One-time Special Discount	Total Monthly Discount	Discounted Monthly Renewal Price
410	2	$ 2,029.00	$ 54.00	$ 995.00	$ 1,049.00	**$ 980.00**
TOTALS	**2**	**$ 2,029.00**	**$ 54.00**	**$ 995.00**	**$ 1,049.00**	**$ 980.00**
					51.70%	

SERVICE PROVISION:	Start Date	October 1, 2025	End Date*	September 30, 2026

COMMENTS:

* All agreements end on the last calendar day of the month. More info

- Invoices/Fees are charged on a monthly basis which is calculated based on a 30-day month. More info
- Arefundable service retainer equivalent to 2 x monthly office fee will be payable. More info

Promotion: Any promotion or discount is for the initial term of the agreement.

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AGREEMENT TO ARBITRATE/CLASS ACTION WAIVER: YOU AND WE MUTUALLY AGREE TO WAIVE OUR RESPECTIVE RIGHTS TO RESOLVE DISPUTES IN A COURT OF LAW BY A JUDGE OR JURY AND AGREE TO RESOLVE ANY DISPUTE BETWEEN US BY BINDING ARBITRATION, except as expressly provided in this paragraph. Any dispute or claim relating in any way or arising out of this Agreement shall be resolved by binding arbitration administered by the American Arbitration Association in accord with its Commercial Arbitration Rules (available at www.adr.org), except that You or We may assert claims in small claims court and We may pursue a court action to remove You if You do not leave when this Agreement terminates (and You may pursue a court action to prevent Your removal). The arbitrator, and not a court of law, shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability, or formation of this agreement to arbitrate, and shall conduct the arbitration on an individual basis only and not as a class or representative action. You and We acknowledge that this Agreement is governed by the Federal Arbitration Act and will survive after this Agreement terminates or your relationship with Us ends.

CLASS ACTION WAIVER: YOU UNDERSTAND AND AGREE THAT YOU AND WE MAY EACH BRING CLAIMS AGAINST THE OTHER, WHETHER IN COURT OR ARBITRATION, ONLY IN AN INDIVIDUAL CAPACITY AND NOT ON A CLASS, COLLECTIVE ACTION, OR REPRESENTATIVE BASIS, AND EXPRESSLY WAIVE THE RIGHT TO PURSUE OR HAVE A DISPUTE RESOLVED AS A PLAINTIFF OR CLASS MEMBER IN ANY PURPORTED CLASS, COLLECTIVE OR REPRESENTATIVE PROCEEDING.

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CONFIRMATION NO : R-3481596

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Exhibit 10.45

AMENDMENT NO. 1 TO NOTES PURCHASE AND EXCHANGE AGREEMENT

This Amendment No. 1 to Notes Purchase and Exchange Agreement (this "Amendment") is entered into as of February 25, 2026 (the "Amendment Date") by and among (i) LiveChain, Inc., a Nevada corporation ("LICH"); (ii) LICH AI, Inc., a Delaware corporation and a wholly owned subsidiary of LICH ("Buyer'); and (iii) Remus Capital Series B II, L.P., a Delaware limited partnership ("Remus"). Each of LICH, Buyer, and Remus are referred to herein as a "Party" and together as the "Parties".

WHEREAS, the Parties are all of the Parties to the Notes Purchase and Exchange Agreement, dated as of February 20, 2026 (the "Original Agreement") and now desire to amend the Original Agreement, and pursuant to the provisions of Section 9.03 of the Original Agreement it may be amended in a writing executed by the Parties;

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth herein, as well as other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties agree as follows:

1. Defined Terms. Capitalized terms used herein without definition shall have the meanings given in the Original Agreement.

2. Amendments. Pursuant to the provisions of Section 9.03 of the Original Agreement, the Original Agreement is hereby amended as follows:

   (a) The date February 20th, 2026 in Section 5.03(a) of the Original Agreement is hereby amended to be March 8, 2026.

   (b) The date February 20, 2026 in Section 7.01(b) of the Original Agreement is hereby amended to be March 8, 2026.

   (c) The Parties acknowledge and agree that the Original Agreement made reference in certain sections to the "Remus Stockholder Approval", but such reference was a typographical error, and therefore (i) the phrase "(notwithstanding the prior receipt of Remus Stockholder Approval)" in Section 7.01(d) of the Original Agreement is hereby deleted, and (ii) the phrase "; provided, however, that in the event that Remus has received Remus Stockholder Approval, no amendment shall be made to this Agreement that requires the approval of Remus Stockholders under applicable Law without obtaining Remus Stockholder Approval of such amendment" in Section 9.03 of the Original Agreement is hereby deleted.

3. Remainder In Effect. Other than as amended herein, the Original Agreement shall remain in full force and effect. As of and following the Amendment Date, any reference in the Original Agreement to the "Agreement" shall be deemed a reference to the Original Agreement as amended by this Amendment.

4. Miscellaneous.

   (a) This Amendment, and any dispute, controversy or claim arising out of, relating to or in connection with this Amendment, including, without limitation, tort claims, statutory claims and contract claims, shall be interpreted, construed, governed and enforced under and solely in accordance with the substantive and procedural laws of the State of Delaware in each case as in effect from time to time and as the same may be amended from time to time, without application of the conflicts of laws provisions and as applied to agreements performed wholly within the State of Delaware.

   (b) This Amendment may be executed in multiple counterparts, each of which shall be deemed an original and all of which taken together shall be but a single instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned have caused this Amendment to be executed by their respective duly authorized officers to be effective as of the Amendment Date.

LiveChain, Inc.

By: */s/ Venkat Nelabhotla*
Name: Venkat Nelabhotla
Title: Chief Executive Officer

LICH AI, Inc.

By: */s/ Venkat Nelabhotla*
Name: Venkat Nelabhotla
Title: Chief Executive Officer

Remus Capital Series B II, L.P.

By: Remus Capital Series B II GP, LLC
Its: General Partner

By: */s/ Krishna Gupta*
Name: Krishna Gupta
Title: Managing Member

Exhibit 21.1

List of Subsidiaries

LiveChain, Inc. (Nevada)
ReShape Costa Rica Sociedad de Responsabilidad Limited (Costa Rica)
ReShape Lifesciences Australia Pty Ltd (Australia)
ReShape Lifesciences Netherlands B.V. (Netherlands)
Vyome Therapeutics Limited (India)
Vyome Therapeutics, Inc. (Delaware)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-3 (No. 333-279231, 333-287168, and 333-291320) and Form S-8 (No. 333-291511) of Vyome Holdings, Inc of our report dated March 17, 2026, relating to the consolidated financial statements which appear in this Form 10-K.

/s/ Kreit & Chiu CPA LLP

Los Angeles, California
March 17, 2026

Exhibit 31.1

CERTIFICATIONS

I, Venkat Nelabhotla, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vyome Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Venkat Nelabhotla

Venkat Nelabhotla
President and Chief Executive Officer

Date: March 18, 2026

Exhibit 31.2

CERTIFICATIONS

I, Robert Dickey IV, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vyome Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Robert Dickey IV

Robert Dickey IV
Interim Chief Financial Officer

Date: March 18, 2026

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Vyome Holdings, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Venkat Nelabhotla, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Venkat Nelabhotla
Venkat Nelabhotla
President and Chief Executive Officer

Date: March 18, 2026

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Vyome Holdings, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Dickey IV, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Robert Dickey IV
Robert Dickey IV
Interim Chief Financial Officer

Date: March 18, 2026