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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2020
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: 001-37897

OBALON THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware (State of Incorporation)	**26-1828101** (I.R.S. Employer Identification No.)
5421 Avenida Encinas, Suite F Carlsbad, California (Address of Principal Executive Offices)	**92008** (Zip Code)

(760) 607-5164
(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value per share	OBLN	The Nasdaq Stock Market LLC

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 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 and pursuant to Rule 405 of Regulation S-T 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 Securities Exchange Act of 1934.

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. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $4.3 million, based on the closing price of the Registrant's common stock of $0.71 as reported by The NASDAQ Global Market as of June 30, 2020. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose. The number of shares of common stock held by non-affiliates excluded 1,623,643 shares of common stock held by directors, officers and affiliates of directors. The number of shares owned by affiliates of directors was determined based upon information supplied by such persons and upon Schedules 13D and 13G, if any, filed with the SEC. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant, that such person is controlled by or under common control with the Registrant, or that such persons are affiliates for any other purpose.

Total shares of common stock outstanding as of the close of business on March 4, 2021 was 10,020,068 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive Proxy Statement for the 2021 Annual Meeting of Stockholders, which proxy statement will be filed not later than 120 days after the end of the fiscal year covered by this report.

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PART I

Summary of Risk Factors

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. Among others, and including those described in the section entitled "Item 1A. Risk Factors" in Part I of this Annual Report, these risks include:

- The conditions under the Merger Agreement may not be satisfied or waived and there can be no assurance that the Merger will be consummated.
- Although an application will be filed for the continued listing of our common stock on The Nasdaq Capital Market in connection with the Merger, there can be no assurance that our common stock will be so listed or, if listed, that the Combined Company following the Merger will be able to comply with the continued listing standards.
- The pendency of the Merger could materially adversely affect our business, financial condition, results of operations or cash flows.
- If the Merger is consummated, the composition of the board of directors and management of the Combined Company will be comprised of the current board of directors and management of ReShape, none of our directors, officers or employees will continue with the Combined Company and our current stockholders will not have a majority ownership and voting interest in the Combined Company, which may affect the strategy and operations of the Combined Company.
- Failure to consummate the Merger could negatively impact our future stock price, operations and financial results.
- We have suspended or terminated essentially all of our commercial efforts, shut down our manufacturing operations and terminated nearly all of our employees, and we cannot assure you when, if ever, these efforts will recommence.
- If we are unable to complete the Merger with ReShape and, in the alternative unable to secure additional financing on favorable terms, or at all, we could be forced to sell all or portions of our business, liquidate all or some of our assets or seek bankruptcy protection to protect stakeholder value.
- We have temporarily ceased our efforts to seek third-party reimbursement and are focused primarily on the successful close of the Merger with ReShape. If the Merger does not close and we are able to continue to operate as a standalone Company, our strategy to attain coverage and reimbursement by third-party payors may not be successful and will subject us to new risks, some of which we may not yet have identified.
- If we are unable to reestablish commercial operations, including sales, marketing, manufacturing and distribution capabilities, whether after the completion of the Merger with ReShape, on our own or in collaboration with third parties, we may not be successful in commercializing our products.
- We have received funding under the Coronavirus Aid, Relief and Economic Security (CARES) Act.
- We have limited operating experience and a history of net losses, and we recently discontinued all of our commercial operations.
- Our business is entirely dependent on sales of the Obalon Balloon System, which we are currently not manufacturing, marketing or selling.
- We have historically maintained a high level of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges especially if we restart commercial operations and manufacturing in the future.
- Physicians have been slow to adopt and use intragastric balloons, and adverse events or other negative developments involving other companies' intragastric balloons or other obesity treatments in the past or future may further slow patient adoption and negatively impact our financial performance and strategic options, and this could continue into the future.

- The efficacy of our Obalon Balloon System depends on patient compliance with a moderate intensity diet and behavior modification program. If patients are unwilling to make dietary and behavioral changes, patient outcomes may suffer which could has negatively impacted perception of our product in the marketplace in the past and could in the future if the Obalon Balloon System is commercialized again.
- Patients may experience serious injury related to the device or procedures as the result of the misuse or malfunction of, or design flaws in, our products, that could expose us to expensive litigation, divert management's attention and harm our reputation and business.
- We depend on third-party suppliers, including single source suppliers, and we have not ordered from those suppliers in approximately one year and they may not be willing or able to reinitiate supply of key materials and components to Obalon.
- We have dramatically reduced our senior management team to only two full-time employees and we cannot assure you that we have or would be able to attract sufficient resources to manage our current operations or restart commercialization of the Obalon Balloon System.
- If patients using our products experience adverse events or other undesirable side effects, regulatory authorities could withdraw or modify our commercial approvals, which would adversely affect our reputation and commercial prospects and/or result in other significant negative consequences.
- The FDA and other regulatory agencies actively enforce the laws and regulations governing the development, approval and commercialization of medical devices. If we are found to have failed to comply with these laws and regulations, we may become subject to significant liability.
- If we fail to comply with healthcare regulations and fraud and abuse laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.
- Material modifications to our Obalon Balloon System and Obalon Navigation System may require new premarket approvals and may require us to recall or cease marketing our Obalon Balloon System until approvals are obtained.
- Risks related to our intellectual property could materially adversely impact our business, competitive position, financial condition, and results of operations.
- The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.
- If we fail to meet all applicable Nasdaq Global 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.
- Current and future litigation could have a material adverse effect on our business and results of operations.

Forward-Looking Statements

This Annual Report on Form 10-K, or this Annual Report, including the sections entitled "Business," "Risk factors," and "Management's discussion and analysis of financial condition and results of operations" contains forward-looking statements. The words "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan" "expect," "seek," and similar expressions that convey uncertainty of future events or outcomes, are intended to identify forward-looking statements.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk factors" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee you that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the SEC with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

ITEM 1. Business

BUSINESS

OVERVIEW

We are a vertically integrated medical device company focused on developing and commercializing innovative medical devices to treat people with obesity. Our current product offering is the Obalon Balloon System, the first and only U.S. Food and Drug Administration, or FDA, approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in patients with obesity. We believe the Obalon Balloon System offers patients and physicians benefits over prior weight loss devices including, but not limited to, clinically meaningful weight loss, a favorable safety profile, improved patient tolerability and comfort, progressive weight loss with durable results, simple and convenient placement, and potentially attractive economics.

The Obalon Balloon System is FDA approved for temporary use to facilitate weight loss in adults with obesity having a body mass index, or BMI, of 30 to 40, or approximately 30 to 100 pounds overweight, who have failed to lose weight through diet and exercise. The system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed. We believe the Obalon Balloon System provides a cost-effective, non-surgical and reversible treatment for weight loss solution in an outpatient setting.

The Obalon Balloon System consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Obalon Navigation System console, which is a combination of hardware and software used to track and display the location of the balloon during placement without x-ray; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas. Placement of a balloon typically occurs in less than 15 minutes and can be accomplished in an outpatient setting without the need for anesthesia or sedation. Patients receive a total of three balloons over the course of eight to 12 weeks and all balloons are removed six months after the first balloon is placed.

In clinical studies, the Obalon Balloon System has demonstrated clinically meaningful weight loss with durable results. In our published pivotal SMART trial, patients in the Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham-control group, with an average of 15.1 pounds of weight loss, resulting in an average 6.9% reduction in total body weight and an average 2.4 point decrease in BMI. In the study, 66.7% of patients lost at least 5% of their total body weight and the study showed statistically significant improvements in cardiometabolic

risk factors, including fasting glucose, systolic blood pressure, cholesterol and triglycerides. Patients in the treatment group were followed for 48 weeks and showed, on average, that 89.5% of the weight loss achieved during the initial 24-week balloon treatment period was maintained at 48 weeks, or 24 weeks after the balloons were removed.

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

We commenced U.S. commercialization of our prior generation Obalon balloon system in January 2017. In March 2020, we announced that the overall economic uncertainty, the restriction on elective procedures and the specific directives issued by the Governor of California as a result of the COVID-19 pandemic had a significant impact on our business. As a result, we halted sales to new patients in our Obalon-branded retail treatment centers, terminated expansion plans for additional retail centers, subsequently closed the two retail treatment centers we had opened and halted manufacturing. Additionally, since August 2020, we have only had two full-time employees: Andy Rasdal, our President and Chief Executive Officer, and Nooshin Hussainy, our Chief Financial Officer. Although we scaled back operations, we continued to strive to execute on our corporate and strategic objectives. For example, we continue to pursue third-party reimbursement of the Obalon Balloon System, explore strategic alternatives, tend to our obligations to care for patients who had been treated at our Obalon-branded retail treatment centers, follow-up on and support product-related issues involving customers that have used Obalon products, and review and comply with our regulatory obligations, including FDA and SEC requirements.

Given those impacts and the significant concern about an economic recovery that would allow consumers to feel confident enough to spend on a cash-pay procedure like the Obalon Balloon System, we do not currently plan to re-open our retail treatment centers, re-initiate our retail treatment center expansion plans, or plan to ship orders to U.S. customers or our former international distributor. As a result, we would not expect to report any new revenue for the foreseeable future.

In March 2020, and again in September 2020, we engaged Canaccord Genuity to serve as our financial advisor related to strategic alternatives.

On January 19, 2021, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Optimus Merger Sub, Inc., a Delaware corporation and our direct, wholly owned subsidiary ("Merger Sub") and ReShape Lifesciences, Inc., a Delaware corporation ("ReShape"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions specified therein, Merger Sub shall be merged with and into ReShape, with ReShape surviving as a wholly owned subsidiary of Obalon (the "Merger"). Pending the outcome of the Merger with ReShape, we may continue to pursue third-party reimbursement of the Obalon Balloon system.

OUR SOLUTION

We have developed our Obalon Balloon System to overcome the limitations of prior devices intended to treat weight loss, including traditional liquid-filled intragastric balloons. Based on our clinical data and commercial experiences, we believe the Obalon Balloon System provides the following benefits to our patients and their physicians:

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

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

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

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

OUR STRATEGY

Given the impacts of COVID-19 on our business and the significant concern about an economic recovery that would allow consumers to feel confident enough to spend on a cash-pay procedure like the Obalon Balloon System, our primary strategy has been to identify a strategic alternative that would be in the best interests of our stockholders. We cannot predict whether, or when, we might restart our commercial operations. If we restart our commercial operations, we expect to focus our strategy on:

- ***Reestablishing a sales marketing organization.*** In order to market our Obalon Balloon System, we will need to reestablish our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services. We would expect to evaluate a direct sales organization, the use of company-owned retail centers or other possible sales and marketing structures, including third parties, to further commercialization efforts.

- ***Leveraging our prior manufacturing capabilities.*** We have built a highly leverageable manufacturing facility at our headquarters in Carlsbad, California, where prior to the suspension of our operations in March 2020 we designed, developed and manufactured a majority of our products in-house while using some components and sub-assemblies provided by third-party suppliers. We believe that controlling the manufacturing and assembly of our products allows us to innovate more quickly and more cost-efficiently, while producing higher quality products than if we outsourced manufacturing.

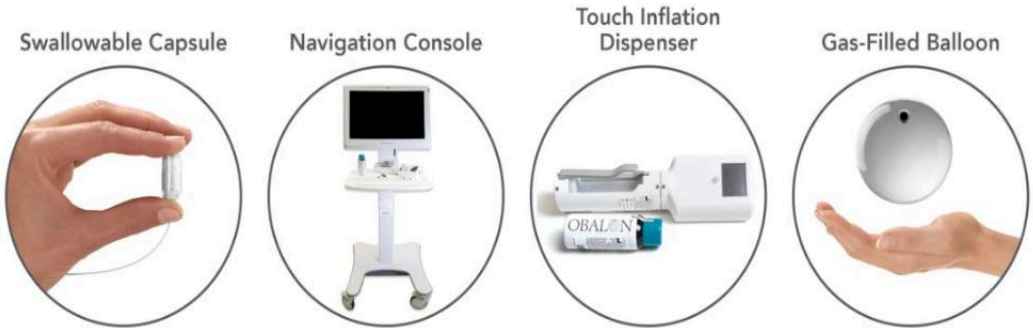
- ***Protecting and expanding our strong intellectual property portfolio.*** We have developed a strong portfolio of issued patents and pending applications that protect our products and technology. We believe we have also developed know-how critical to creating current and future products that we hold and protect as trade secrets. We intend to aggressively protect and enforce our intellectual property.

- ***Obtaining coverage and reimbursement from third-party payors.*** During the second quarter of 2020, we developed a strategy to obtain coverage and reimbursement from third-party payors, which we believe could address one of the

largest barriers to patient and physician adoption of the Obalon Balloon System. Historically, we have utilized both a direct to physician model and a Company-managed Obalon-branded retail treatment center strategy. Both of these commercial strategies utilized a patient cash-pay model, with varying degrees of success.

OUR PRODUCTS AND TECHNOLOGY

The main components of our current generation Obalon Balloon System consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Obalon Navigation System console, which is a combination of hardware and software used to dynamically track and display the location of the balloon during placement; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas.



Capsule, balloon and microcatheter technology

Dissolvable capsule

We designed the capsule to be large enough to accommodate the folded balloon, yet small enough to be swallowed. The capsule is titrated to optimize dissolution timing. If the capsule dissolves too quickly, the balloon could be prematurely released before entering the stomach, and if too slowly, the patient and physician are inconvenienced by having to wait longer to inflate the balloon.

Balloon film

Our film is a coextruded, multilayer polymer consisting primarily of nylon and polyethylene. We designed the film to be thin enough to fit into a swallowable capsule, yet stable enough to withstand the chemical and mechanical forces in the stomach. Our film is biocompatible, cost-effective to manufacture, puncture and abrasion resistant, smooth and atraumatic to the stomach's lining and able to appropriately retain gas.

Balloon valve

Our balloon valve is an innovative combination of materials, including silicone and titanium, designed to be highly reliable. The valve is small enough to fit into a swallowable capsule and radiopaque for visibility under digital imaging. A key feature of our valve is the ability to effectively reseal after the inflation catheter is removed to prevent leaks.

Microcatheter

Our microcatheter is designed to quickly and reliably inflate the Obalon balloon. It is small, flexible and smooth in order to minimize any potential discomfort to the patient during balloon placement. The catheter utilizes a hydrophilic coating to reduce friction during swallowing.

Inflation system

The Obalon Touch Inflation Dispenser is a semi-automated, hand-held inflation device that provides real-time balloon pressure measurements to confirm that the Obalon balloon is both properly placed and correctly inflated in the stomach. The Obalon Touch Inflation Dispenser automates several steps of the balloon inflation process and eliminates the need for altitude pre-programming. The Obalon Navigation System is intended to be commercially launched exclusively with the Obalon Touch Inflation System.

Proprietary gas

The Obalon balloon is inflated with our proprietary mix of gas, which, in combination with the permeability of the balloon film and the stomach gases, enables the balloon to remain inflated for the full six-month treatment period.

The Obalon Navigation System

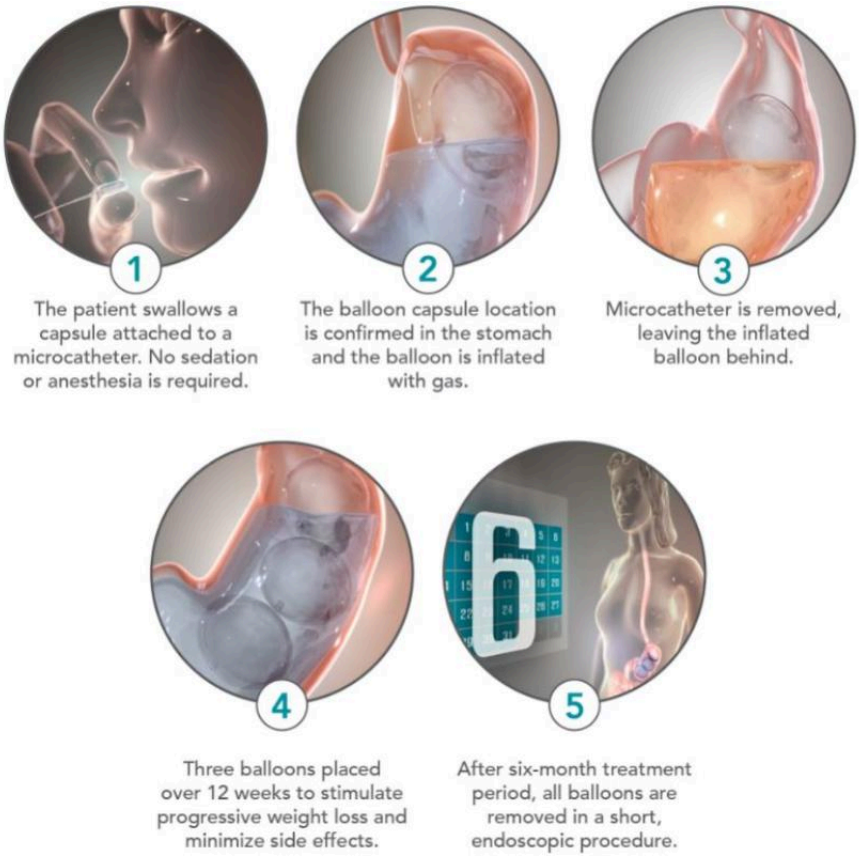
The Obalon Navigation System consists of a Navigation console and the Obalon Touch Inflation Dispenser. The Obalon Navigation System console is a portable device consisting of hardware and software that are used to track and display the Obalon balloon during administration. The Obalon balloon is placed utilizing the Obalon Navigation System console and Obalon Touch Inflation Dispenser. The current generation of the Obalon balloon is only compatible with the Obalon Navigation console and Obalon Touch Inflation Dispenser and is not compatible with any prior generation Obalon balloon systems.

The Obalon Balloon treatment

Placement of the Obalon balloon typically occurs in less than 15 minutes and can be accomplished in an outpatient setting. To place the Obalon balloon, the patient swallows the capsule, which has the Obalon balloon folded inside, with a glass of water. No sedation or anesthesia is required. Once swallowed, placement of the capsule is confirmed in the stomach using the Obalon Navigation System. Balloon placement can also be confirmed using x-ray. The microcatheter, which is attached to the Obalon balloon, is then connected to the Obalon Touch Inflation Dispenser. The Touch inflation systems provides real-time pressure measurements to confirm that the Obalon balloon is both properly placed and able to be correctly inflated in the stomach. A pre-filled canister of gas is inserted into the inflation system and then the gas is discharged to fill the balloon to a volume of 250cc. Once the inflation of the Obalon balloon is confirmed, the microcatheter is detached from the balloon via hydrostatic pressure and is removed through the patient's mouth. The patient is intended to return two more times over the following eight to 12 weeks to receive a second and third Obalon balloon, expanding total balloon volume within the stomach to approximately 750cc.

All of the balloons are removed in a single procedure no more than six months after the placement of the initial balloon. The balloons are removed endoscopically under light conscious sedation, using standard commercially-available endoscopy tools. The endoscopic procedure to remove the balloons typically requires approximately 15 minutes.

The following pictures depict the treatment steps of the Obalon Balloon System:



Research and development

As of December 31, 2020, we had no employees focused on research and development. Research and development expenses for the years ended December 31, 2020 and 2019 were $2.5 million and $6.9 million, respectively.

CLINICAL TRIALS AND DATA

SMART Trial

Based on our clinical data, we believe our Obalon balloon has the potential to offer a compelling combination of efficacy and safety. We have evaluated various versions of our Obalon Balloon System in several clinical trials. Based on the results of our U.S. pivotal trial, the SMART trial, we received FDA approval for our current Obalon Balloon System in September 2016. The data was published in Surgery for Obesity and Related Diseases in September 2018. The SMART trial met its primary weight loss endpoints, demonstrated a strong safety profile, continued weight loss over the full six-month treatment period, showed statistically significant differences in metabolic profiles and demonstrated that patients were able to maintain most of the weight loss for at least six months following the removal of the Obalon balloons.

The SMART trial was a prospective, double-blinded, multi-center, randomized (1:1), parallel-group, active sham-controlled trial of 387 patients. The Obalon treatment group received three balloons placed individually at approximately week zero, week three and week 12. Alternatively, the sham-control group received placebo capsules with microcatheters and were led to believe in a mock placement that a balloon was placed and inflated in their stomachs at week zero, week three and week 12. Patients were given minimal diet counseling of 25 minutes every three weeks in order to isolate the impact of the Obalon balloon on weight reduction.

The trial was conducted by both bariatric surgeons and gastroenterologists at 15 U.S. centers. The trial evaluated a co-primary endpoint comprised of (i) a minimum difference in mean percent TBL between the Obalon treatment group and sham-control group of at least 2.1% and (ii) achievement by at least 35% of the Obalon treatment group patients of at least 5% TBL at the end of six-months of treatment. Additional observational measures included metabolic metrics and weight loss maintenance after removal of balloons. The median time for each balloon placement was nine minutes, while the median balloon removal time for three balloons was 14 minutes.

Results from the SMART trial met both the co-primary endpoints. The per protocol analysis included 366 patients (185 in the Obalon treatment group and 181 in the sham-control group) and showed patients in the Obalon treatment group achieved mean TBL of 6.86%, or 15.06 lbs, vs 3.59%, or 7.77 lbs, in the sham-control group, showing a difference of 3.28%, or 7.28 lbs. The following table summarizes average percentage of TBL, percentage of excess weight loss, or EWL, and weight loss (in pounds) for the Obalon treatment group and the sham-control group in the SMART trial. All weight loss metrics below were statistically significant.

Weight Loss Metric Per Protocol Cohort	Obalon Treatment Group (N = 185)	Sham-Control Group (N = 181)	Difference	p-value
Percent TBL	-6.86	-3.59	-3.28	0.0261
Percent EWL	-25.05	-12.95	-12.09	< 0.0001
Weight Loss (lbs.)	-15.06	-7.77	-7.28	< 0.0001

In addition, 64.9% of the Obalon treatment group patients met or exceeded the 5% TBL endpoint whereas only 32.0% of the sham-control group met or exceeded 5% TBL. The following table summarizes the 5% TBL responder rates for the Obalon treatment group and the sham-control group in the SMART trial.

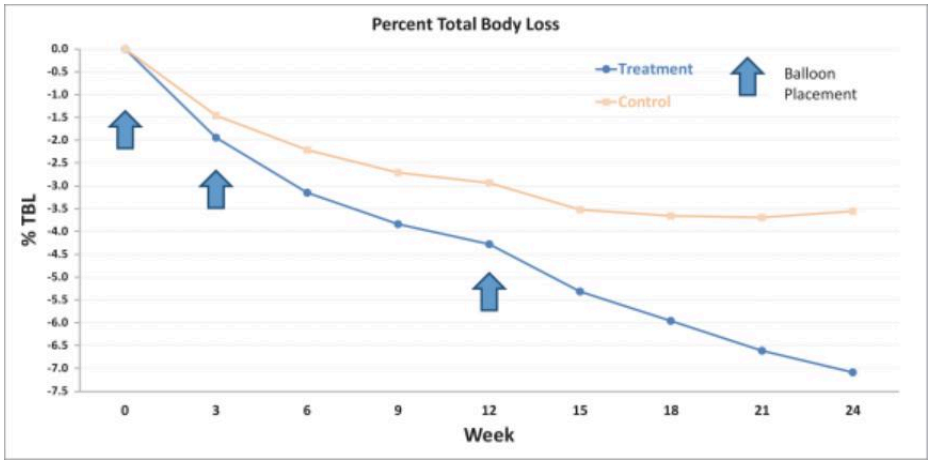
Main Analysis of -5% TBL Responder Rate	Estimate
Obalon Treatment Group—Per Protocol Cohort*	120 / 185 (64.9)%
Sham-Control Group	58 / 181 (32.0)%
Difference (Treatment less Control)	32.8%

* p-value <0.0001

The following table summarizes the various responder rate thresholds for the Obalon treatment group and the sham-control group in the SMART trial.

Responder Rate Threshold (-%TBL)	Obalon Treatment Group	Sham-Control Group
-6 %	98 / 185 (53.0)%	47 / 181 (26.0)%
-7 %	81 / 185 (43.8)%	38 / 181 (21.0)%
-8 %	68 / 185 (36.8)%	35 / 181 (19.3)%
-9 %	55 / 185 (29.7)%	29 / 181 (16.0)%
-10 %	49 / 185 (26.5)%	23 / 181 (12.7)%

Notably, the Obalon treatment group demonstrated a progressive weight loss profile for the duration of the six-month therapy period. The following chart shows percent TBL by week for the Obalon treatment group and sham-control group. The arrows represent the average week of each balloon placement.



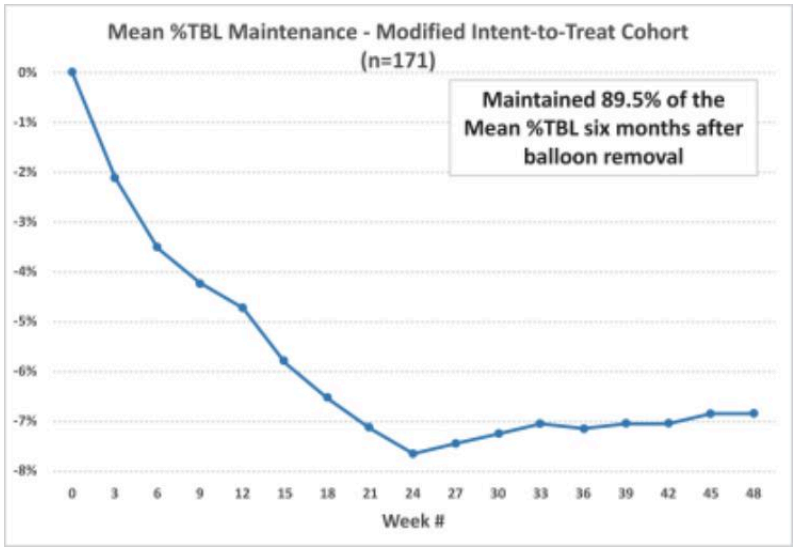
In addition, nearly all patients in the Obalon treatment group, including patients in the bottom 25% of the group, achieved TBL, EWL and weight loss and a reduction in BMI. The table below summarizes the mean, the average of the top 25% of the results, the average of the bottom 25% of the results and the single best changes in TBL, EWL, weight loss and BMI achieved by patients in the Obalon treatment group.

Weight Loss Metric	Mean		Average Top 25	%	Average Worst 25	%	Single Best	
Percent TBL	-6.9	%	-10.2	%	-3.6	%	-19.3	%
Percent EWL	-25.1	%	-36.3	%	-12.3	%	-80.7	%
Weight Loss (lbs.)	-15.1		-21.8		-7.4		-49.7	
BMI Change	-2.4		-3.6		-1.3		-7.1	

In an observational analysis at six months, the Obalon treatment group also demonstrated statistically significant improvements in systolic blood pressure, fasting glucose, total cholesterol and triglycerides compared to both their own baseline measures and to the sham-control group.

At the conclusion of the six-month treatment period, the Obalon treatment group patients continued with the standardized behavior modification program for six additional months after the Obalon balloon removal. An additional observational data analysis of the subjects who lost weight in the first six months of the study and were evaluated for up to an additional six months, suggests that, on average, 89.5% of the weight loss was maintained six months after balloon removal. The following graph depicts the weight loss maintained for the one-year period in the Obalon treatment group.

We did not continue to collect data from patients in the sham-control group who received the Obalon balloons subsequent to balloon removal.



As part of the SMART trial, we actively solicited patients to provide details of any adverse events, or AEs, by contacting all patients 24 hours after each Obalon balloon placement and balloon removal as well as at every office visit. All AEs were first assigned a device-relatedness and a pre-defined severity rating. Mild events did not require intervention, required homeopathic remedies (including chamomile tea, peppermint oil tea and Altoids) or required over the counter remedies to treat and resolve the events. Moderate severity events required a prescription medication to treat and resolve the event. Severe events required medical intervention beyond a prescription medication.

In our SMART trial, only one out of 336 patients (0.3%) receiving Obalon balloons in both phases experienced a SADE. The event was described as peptic ulcer disease, or bleeding. The patient was hospitalized, and after stabilization, the patient was discharged from the hospital without sequelae. During the Obalon balloon therapy period the subject underwent an outpatient total knee replacement surgery. During the surgery and as part of post-operative recovery, the subject was prescribed both a high dose of nonsteroidal anti-inflammatory drugs, or NSAIDs, and aspirin, both of which are contraindicated for use with each other as well as for use in conjunction with the Obalon Balloon System. The SADE event was determined to be “possibly,” but not “probably,” device-related by the investigator since concomitant high dose NSAID and aspirin use is also known to cause peptic ulcer disease. The investigator felt that the NSAID and aspirin use was the primary cause of the event but could not rule out the balloons completely. The patient previously had no ulcers per the upper gastrointestinal screen performed at time of enrollment and was not taking medications prior to surgery.

In our SMART trial, there were no surgical removals or other hospitalizations due to a SADE other than the SADE described above. The most common other adverse device events during balloon placement were abdominal pain (72.6% of patients), nausea (56.0% of patients) and vomiting (17.3% of patients), all of which were classified as mild or moderate.

Commercial-Use Patient Registry

In order to closely monitor the safety, efficacy and quality of the Obalon Balloon System in actual commercial use, we created an online clinical performance database, or registry. All physicians and institutions using the Obalon Balloon

System have been encouraged to enter their patient data in the registry and compare their performance to national and regional data. The data collected in the registry includes gender, initial height and weight, weights at each subsequent balloon placement, weight at removal, adverse events occurring during the treatment, and product quality and performance.

Data on the first full year of commercialization of the Obalon Balloon System was accepted for publication in December 2018 in Surgery for Obesity and Related Diseases. Data on demographics, balloon placement timing, weight loss, adverse events, and product performance were prospectively captured in the registry and retrospectively analyzed on 1,387 consecutive patients who initiated treatment in the first year of commercialization at 108 treating sites. A retrospective analysis of 1,343 (97%) patients entered who met the predefined analyses protocol definitions was approved by an Institutional Review Board. This data is self-reported by the physicians or institutions and we do not perform a formal audit of the data. However, the registry was validated and contains embedded edit checks to ensure data accuracy and completeness.

Demographics

Mean baseline demographics were: age 45.7±10.8 years, BMI 35.4±5.4 kg/m2, height 65.9±3.5 inches, weight 219.5± 42.9 lbs., female 78.6% and white 66.8%.

Safety

There were no deaths or unanticipated adverse events reported. Two serious adverse events were reported, corresponding to 0.15% of patients. There were 308 non-serious adverse events reported in 14.2% of the patients. The most frequent adverse events reported were abdominal pain (5.3%), nausea (4.7%), vomiting (2.3%) and abdominal distension (1.0%). The remaining adverse events were less than 1.0%.

Weight Loss

The weight loss for patients with intended use (BMI 30-40 kg/m2 with 3 balloons for ≥ 20 weeks of therapy) was 21.3 ± 13.5 lbs., 10.0% ± 6.1% of total body weight loss (TBWL), 38.3% ± 25.3% excess weight loss (EWL) and a 3.4 ± 2.1 reduction in BMI. Of note, the top quartile of those patients lost an average of 38.2 pounds, resulting in a 17.2% reduction in total body weight and a 6.1 point decrease in BMI compared to baseline values. Average weight loss across all patients with a BMI>25 was 21.7 lbs resulting in a percent total body loss of 9.9%. The top quartile of all patients with a BMI>25 lost an average of 39.0 lbs., resulting in a 16.8% reduction in total body weight and a 6.2 point decrease in BMI compared to baseline values. We believe the outcome data collected in this registry is the largest known registry of an approved endoscopic bariatric therapy to date, including intragastric balloons, and provides evidence of effective weight loss and safety in a real-world, commercial setting. The data captured in the registry for the first year of commercialization (January 9, 2017 to December 31, 2017) was accepted for publication in the journal Surgery for Obesity and Related Diseases.

In early November 2019, we discontinued the commercial use registry.

Commercial safety experience

As of December 31, 2020, we have had a minimal number of SADEs reported to us in commercial use. Since we began selling in United States in January 2017, we have reported adverse events relating to potential or actual patient injuries associated with use of the Obalon balloon in the FDA's MAUDE database.

Post-approval study - Obalon Balloon System

To help assure the continued safety and effectiveness of the Obalon Balloon System, the FDA has required a post-approval study as a condition of approval under 21 CFR 814.82(a)(2). As part of our PMA approval, we agreed with the FDA to conduct a post-approval study that will evaluate 200 patients who will be enrolled at a maximum of 15 sites in the United States. The study is a prospective, open-label, single-arm, 12-month follow-up study in which patients will be

treated during the first six months with placement of up to three Obalon balloons in conjunction with a moderate intensity weight loss and behavioral modification program standardized throughout the sites, followed by observational evaluation for an additional six months after device removal. The primary endpoint is to evaluate the safety of the Obalon Balloon System by assessing the rate of device- or procedure-related serious adverse events. We are required to submit an Interim Post-Approval Study Status Report every six months after the date of PMA approval for the first two years of the study and annually thereafter until approximately 200 patients have completed the study. We have completed enrollment of the 200 patients and would expect to complete the final follow-up on all patients during 2021.

Post-approval study - Obalon Navigation-Touch System (NTS)

To help assure the continued safety and effectiveness of the Obalon Navigation System, the FDA has required a post-approval study as a condition of approval under 21 CFR 814.82(a)(2). As part of our PMA approval, we agreed with the FDA to conduct a post-approval study that will evaluate approximately 1,000 commercial patients and up to 4,000 balloon administrations up to 40 clinical sites in the United States. The study will be a prospective, observational, open-label, multi-center study designed to capture additional safety and effectiveness data of the Obalon balloon administration with NTS. The study will have a single cohort group that includes patients who commercially purchased the Obalon Balloon System at clinics and hospitals that uses NTS and have consented to have their data collected to support this study. All activities related to post-administration management, weight loss and removal of the balloons will be conducted in accordance with the commercial Obalon Balloon System device labeling and will not be collected in this study; this study will focus on balloon administrations only. We began patient enrollment for this study in December 2019 and suspended enrollment with the suspension of our commercial operations as a result of the effects of COVID-19. Pending the results of the Merger, we may restart enrollment of this post approval study.

SALES AND MARKETING

In March 2020, we announced that the overall economic uncertainty, the restriction on elective procedures and the specific directives issued by the Governor of California as a result of the COVID-19 pandemic had a significant impact on our business. As a result, we halted sales to new patients in our Obalon -branded retail treatment centers, terminated expansion plans for additional retail centers and subsequently closed the two retail treatment centers we had opened. We have not filled orders to U.S. customers or our former sole international distributor, Al Danah, with whom we terminated our contract. Additionally, since August 2020, we have only had two full-time employees.

Prior to taking these steps, we generally sought to drive consumer awareness and interest in part through multiple efforts that may include digital, offline and social marketing. In the fourth quarter of 2018, we enhanced our capabilities to convert patient interest to treatment by implementing a call center, which we named the Obalon Ambassador Center, with the capabilities to schedule interested patients to see physicians affiliated with the Obalon Center for Weight Loss™ treatment centers. We believed Obalon-managed treatment centers would directly leverage these capabilities and allow us to enhance the patient experience, from initial interest through to the completion of patient therapy. The Company-owned or managed Obalon-branded treatment centers employed a full-time sales professional dedicated to converting interested consumers generated through our internal marketing efforts into prospective patients.

COMPETITION

The medical device industry generally, and the market for weight loss devices specifically, are highly competitive, subject to rapid change and significantly affected by new product introductions, results of clinical research, corporate combinations, actions by regulatory bodies, changes by public and private payers and other factors. Because of the market opportunity and the high growth potential of the non-surgical device market for weight loss and obesity, competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products.

In the United States, our product competes with a variety of pharmaceuticals, surgical procedures and devices for the treatment of obese and overweight people. Large competitors in the surgical segment for weight loss and obesity include Ethicon Inc. (subsidiary of Johnson & Johnson), Medtronic plc, Apollo EndoSurgery, Inc., and ReShape LifeSciences (LAP-BAND). In addition, we are aware of one FDA approved liquid-filled balloon devices for treating overweight

people that is currently being marketed, the ORBERA Balloon, of which is now owned by Apollo EndoSurgery. Outside of the United States, Allurion Technologies, Inc. has developed a swallowable, passable liquid-filled intragastric balloon that for which they are seeking regulatory approval. Spatz Medical has also developed a liquid-filled intragastric balloon that has been approved for sale in Latin America and Europe and is seeking regulatory approval in the U.S. We also compete against ReShape LifeSciences' LAP-BAND and non-balloon treatments including a technology developed by Gelesis known as the Plenity device that is intended to expand in the stomach by absorbing water to create the feeling of satiety and is currently engaged in a U.S. clinical trial. Additionally, we are aware of numerous companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, any of which, if approved, could compete with us in the future.

At any time, these or other competitors may introduce new or alternative products that compete directly or indirectly with our products and services. They may also develop and patent products and processes earlier than we can or obtain regulatory clearance or approvals faster than us, which could impair our ability to develop and commercialize similar products or services. If clinical outcomes of procedures performed with our competitors' products are, or are perceived to be, superior to treatments performed with our products, sales of our products could be negatively affected and our business, results of operations and financial condition could suffer.

Many of our competitors have significantly greater financial and other resources than we do, as well as:

- well-established reputations and name recognition with key opinion leaders and physician networks;
- an established base of long-time customers with strong brand loyalty;
- products supported by long-term data;
- longer operating histories;
- significantly larger installed bases of equipment;
- greater existing market share in the obesity and weight management market;
- broader product offerings and established distribution channels;
- greater ability to cross-sell products;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives; and
- more experience in conducting research and development, manufacturing, performing clinical trials and obtaining regulatory approvals or clearances.

Competition with these companies could result in significant price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing and future products, which may cause our revenues to decline and harm our business.

In order to compete effectively, we must develop new product offerings and enhancements to our existing Obalon Balloon System, price our product competitively with traditional liquid-filled intragastric balloons and maintain adequate research and development and sales and marketing personnel and resources to meet the demands of the market.

INTELLECTUAL PROPERTY

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights.

It is our policy to require our employees, consultants, contractors, outside scientific collaborators and other advisers to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from using the proprietary rights of third parties in their work for us. We also require third parties that receive our confidential data or material to enter into confidentiality or material transfer agreements.

As of December 31, 2020, we held approximately 33 issued U.S. patents and had approximately 15 pending U.S. patent applications, as well as approximately 31 international patents issued in regions including Europe, Mexico, Australia, Canada, Asia, South America, China and Israel and approximately 46 pending international patent applications in regions including Australia, Canada, Europe, Asia, Mexico, China, Israel, the Middle East and South America. Our issued patents expire between the years 2023 and 2038, and are directed to various features and combinations of features of the Obalon Balloon System technology, including the apparatus for connecting the balloon to an inflation catheter, the structure and composition of the balloon wall, and the composition of the initial fill gas.

Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that does not infringe our patents. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

As of December 31, 2020, we held two registered U.S. trademarks and approximately 41 registered marks in regions including Europe, Brazil, the Middle East, Asia and Mexico. We had three pending U.S. trademark applications and no pending marks outside the United States.

MANUFACTURING

Prior to the suspension of our commercial operations in March 2020, all of our products except the Obalon Navigation System console were manufactured or assembled in-house using components and sub-assemblies at our single-site facility in Carlsbad, California. We rely on single suppliers for the extruded film, swallowable capsule, molded silicone valve used to manufacture our Obalon balloons, the hydrophilic coating for our catheters, the Obalon Navigation System console components and the sensors utilized in the Obalon Navigation balloon catheter. There are minimum purchase requirements and delivery requirements with the supplier for the Obalon Navigation System console and sensor utilized in the Obalon Navigation balloon catheter. Our suppliers for all other components of the Obalon balloon have no contractual obligations to supply us, and we are not contractually obligated to purchase any of our supplies from them. We historically base our order quantities and lead times for components purchased from our suppliers on our forecasts derived from historical demand and anticipated future demand. Lead times for components can vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. These components are critical to our products and there are relatively few alternative sources of supply. We do not carry a significant inventory of these components, and identifying and qualifying additional or replacement suppliers for any of the components or sub-assemblies used in our products could involve significant time and cost, and may delay our commercialization efforts.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the Center for Devices and Radiological Health. We and our component suppliers are required to manufacture our products in compliance with the FDA's Quality System Regulation, or QSR, in 21 CFR part 820 of the Federal Food, Drug and Cosmetic Act. The QSR regulates extensively the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR

through periodic inspections that may include the manufacturing facilities of our subcontractors. Our quality system has undergone periodic FDA audits, the last of which occurred in November 2017, which resulted in no observations.

Although we expect our third-party suppliers to supply us with components that meet our specifications and comply with regulatory and quality requirements, we do not control our suppliers outside of our agreements, as they operate and oversee their own businesses. There is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our needs. Any significant delay or interruption in the supply of components or sub-assemblies, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business. We have experienced and may in the future experience production challenges due to shortages of key components from suppliers.

As a result of the COVID-19 pandemic and accompanying the overall economic uncertainty, the restrictions on elective procedures and the specific directives issued by the Governor of California we ceased manufacturing operations and have not manufactured any products since 2020. If the Merger is consummated and our operations are reopened, we will need to restart our manufacturing operations. We have not ordered from our suppliers since we suspended operations and, if we choose to restart manufacturing, those suppliers may be unwilling or unable to supply us. If we determine to restart commercial operations, we will need to reestablish our supplier and manufacturing capabilities, and likely improve them, in order to satisfy expected demand. We may find that we are unable to successfully manufacture our products in sufficient quantities, on a timely basis and with the expected quality.

GEOGRAPHIC REGIONS

Substantially all of our assets, revenues and expenses for 2020 and 2019 were located in or derived from operations in the United States. In addition, we have had sales through Bader and Al Danah in the Middle East. The distribution agreement with Bader was terminated in December 2019 and the distribution agreement with Al Danah was terminated in 2020. During 2020 and 2019, international revenue accounted for approximately 30.2% and 48.4%, respectively, of our total revenues.

SEASONALITY

We have limited experience selling our product in the United States and have realized significant volatility in quarterly revenues. As a result, we are unable to discern seasonal variations in demand for our products. In the future, seasonal fluctuations in the number of patients seeking treatment and the availability of our physician customers may affect our business.

GOVERNMENT REGULATION

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

Regulatory system for medical devices in the United States

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FFDCA, also referred to as a

510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Device classification

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

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

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

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The investigational device process

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

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study

sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product.

The 510(k) approval process

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

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

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

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

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

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of

information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

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

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

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

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

Obalon Navigation System or any of its components, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

Pervasive and continuing FDA regulation

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

- the FDA's QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval of product modifications;
- medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

In addition, FDA enforces the Medical Device Reporting, or MDR, regulations, which require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Since February 2017, the FDA has issued three separate letters to healthcare providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. We are aware of the filing of additional reports of serious adverse events, including deaths, associated with liquid-filled balloons since the issuance of the FDA letters to healthcare providers. While the advisory letters were specific to liquid-filled intragastric balloons and not the Obalon gas-filled balloons, these letters could create negative perceptions of the entire gastric balloon category which may cause negative consequences for us including requiring additional warnings, precautions and/or contraindications in the labeling than originally required, delaying or denying approval of our future products, or possible review or withdrawal of our current approval. Since we began selling in United States in January 2017, we have reported adverse events relating to patient injuries associated with use of the Obalon balloon in the FDA's MAUDE database.

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

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

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

Regulatory system for medical devices in Europe

The European Union consists of member states residing in the European Union and has a coordinated system for the authorization of medical devices. The European Union Medical Devices Directive, or MDD, sets out the basic regulatory framework for medical devices in the European Union. This directive has been separately enacted in more detail in the national legislation of the individual member states of the European Union.

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

According to the MDD, the Obalon Balloon System, when delivered with a cellulose-based capsule is considered a Class IIb product. We believe the Obalon Navigation System and the Obalon Touch Inflation Dispenser are Class I products not requiring Notified Body approval. Our Medical Device Marketing Authorization under the prior regulation, MDD, was renewed on July 26, 2016 and expires on May 14, 2020. We have not applied for a CE-mark for the Obalon Navigation System and Obalon Touch Inflation Dispenser at this time under the new Medical Device Regulation, or MDR. We have allowed the Obalon balloon CE-mark expire under the previous MDD regulation and have not renewed our agreement with BSI, our Notified Body.

Regulatory frameworks for medical devices in certain countries in the Middle East

Unlike Europe, while the Gulf Cooperation Council, or GCC, jurisdictions often work together to purchase certain medical products in a coordinated fashion for government hospitals, there is not a coordinated system for the

authorization of medical devices. Most GCC jurisdictions require that the official registered distributor of a product be wholly owned by nationals of that particular GCC jurisdiction.

Qatar

Qatar recognizes FDA approvals to be sufficient to establish approval within the country. Obalon had obtained U.S. FDA approval for the products and Al Danah obtained the registration that is necessary to permit the purchase and distribution within Qatar. Al Danah sold product directly to hospitals within Qatar until we terminated our agreement with Al Danah earlier in 2020.

Kingdom of Saudi Arabia, or KSA

The most pertinent regulation is the Interim Regulation for Medical Devices, issued by the Saudi Food & Drug Authority, or SFDA, Board of Directors' Decree number 1-8-1429 dated approximately December 27, 2008 and the implementing regulations of the same. The SFDA is an independent regulatory body that is responsible for the authorization of medical devices, and current guidelines are generally based on pre-existing approval in one of the five founding member nations of the Global Harmonization Task Force, or GHTF, which are Australia, Canada, United States, European Union and Japan. There are no overt requirements for the provision of safety and effectiveness data in the form of clinical trials or other studies but these would likely come as a part of the approvals described above that are used as a basis to support approval within the KSA. The SFDA reserves its rights to require its own independent clinical trials as it deems necessary or appropriate. Regulatory authorization is required for all medical devices, regardless of device class. A potential exception to this requirement is for medical devices that were designed and constructed by local health care facility and staff for internal use. Similar to the United States, the SFDA requires post market surveillance to ensure safety and quality. This program is meant to be conducted by the Authorized Representative. With respect to the use of medical devices, it is the responsibility of the health care institution to inform the manufacturer and the SFDA of any adverse events associated with this use. We previously appointed Al Sultan Saudi Medical Company as our responsible Authorized Representative for the KSA. Our Medical Device Marketing Authorization was renewed on July 26, 2016 however, the relevant distribution agreement was terminated in December 2019. In KSA it is possible for a foreign party to establish a Technical & Scientific Office and register the medical device, while working with a locally licensed Authorized Representative to conduct sales of such approved medical devices.

Kuwait

Medical devices in Kuwait are regulated by the Medicines and Medical Supplies, Pharmaceuticals and Herbal Medicines Registration and Control Administration Department in the Ministry of Health.

In order for any company/manufacturer to sell a medical device in Kuwait, the specific medical device must be approved for use and registered in Kuwait with the Ministry of Health. The manufacturer of the device, through its agent/distributor should submit an application to the Ministry of Health for the approval and registration of the device. The documents required to register a medical device with the Ministry of Health in summary include: (i) the original Manufacturing License and Good Manufacturing Practice certificates; (ii) the original Free Sale Certificate which should mention the trade name, scientific name, indications, and detailed composition for active and inactive ingredients and which should be issued by the health authority in the country of origin of the device; (iii) the status of registration of the product in the country of origin; (iv) the original letter of appointment of an exclusive agent/distributor for the device; (v) a list of countries where the product is registered with registration dates and numbers; (vi) a sample of the product with information about the product on the outer and inner packaging in English or Arabic (the information on the packaging should include: the name of the product, its content/composition, uses, batch number, manufacturing date, expiry date, storage conditions, and instructions on use); (vii) a certificate of analysis of the finished product; (viii) safety and efficacy studies from an approved international authority (and/or clinical studies if applicable); and (ix) any other information the Ministry of Health may require. Once all documents are in order and the Ministry of Health does not require any further information, it will register the device under the names of the manufacturer and the relevant agent/distributor.

The promotion, distribution and sale of medical devices in Kuwait can only be done by a Kuwaiti entity that is appointed by the manufacturer of the device as its exclusive agent/distributor for Kuwait. Such agent/distributor must be authorized by and registered with the Medicines and Medical Supplies, Pharmaceuticals and Herbal Medicines Registration and Control Administration Department in the Ministry of Health and the Ministry of Commerce and Industry to do so. The device may be sold in licensed pharmacies and other places approved by the Ministry of Health.

We previously appointed Bader as our exclusive agent/distributor in Kuwait, however, this distribution agreement was terminated in December 2019.

United Arab Emirates, or UAE

The most pertinent regulation is UAE Federal Law No. 4 of 1983 for the Pharmaceutical Profession and Institutions and to Medical Device Regulations. There are many similarities between the SFDA and the Registration and Drug Control Department that is run out of the Ministry of Health & Prevention of the UAE. Applications for registration of medical devices in the UAE are done with the UAE Ministry of Health Registration & Drug Control Department and must include data on effectiveness in addition to safety (a nod to the requirements of the FDA). The UAE body has its own device classification system that is most closely related to that used by the European Union, defined as class 1, low risk; class 2, medium risk but nonimplantable; class 3, medium risk but implantable; and class 4, high risk. We previously appointed Sohail Faris Medical Equipment Trading as the responsible Authorized Representative for the UAE however, the relevant distribution agreement was terminated in December 2019.

Privacy and security laws

Medical device companies may be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the United States, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and all regulations promulgated thereunder, collectively HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon ‘‘covered entities’’ (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Although we are not a covered entity, we may provide certain services that require the use or disclosure of PHI on behalf of physicians who are covered entities, and we therefore may be considered to be business associates under HIPAA. HIPAA imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions.

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

In addition, certain state and non-U.S. laws, such as the European Union General Data Protection Regulation, or GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Further, ‘‘business associates,’’ defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, are also subject to certain HIPAA privacy and security standards. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate, it may regulate or impact our expected processing of personal information depending on the context. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom’s departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom’s departure from the EU.

Anti-kickback statutes

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

Courts have interpreted the Anti-Kickback Statute quite broadly, holding that the statute will be violated if even one purpose of a payment – though not its sole or primary purpose – is to induce an act prohibited by the statute with a willful intent to act improperly. The statute prohibits many arrangements and practices that are otherwise lawful in businesses outside of the healthcare industry. Prosecutors may infer intent from the surrounding circumstances and, because courts have interpreted the statute to be violated if even one purpose of a payment is to induce the purchase of items or services paid for by federal healthcare programs, prosecutors have broad discretion in choosing arrangements to prosecute under the statute. There are statutory exceptions and regulatory “safe harbors” available to protect certain appropriately structured arrangements that otherwise would implicate the Anti-Kickback Statute. Those who structure their business arrangements to satisfy all of the criteria of a safe harbor are protected from liability under the statute.

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

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

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

False claims laws

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

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

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

Because the Obalon Balloon System is not reimbursed by federal healthcare programs or any other third-party payor, we do not believe that the business generally will be subject to many of these laws unless such reimbursement is obtained in the future.

Transparency laws

The federal Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Patient Protection and Affordable Care Act, or the PPACA, generally requires certain manufacturers of a drug, device, biologic or other medical supply that is covered by Medicare, Medicaid or the Children's Health Insurance Program and applicable group purchasing organizations to report on an annual basis: (i) certain payments and other transfers of value given to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals and (ii) any ownership or investment interest that physicians, or their immediate family members, have in their company. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Under the statute, the federal government makes reported information available to the public. Failure to comply with the reporting requirements can result in significant civil monetary penalties, with additional penalties for the knowing failure to report. Additionally, there are criminal penalties if an entity intentionally makes false statements in the reports. Because the Obalon Balloon System is not covered or reimbursed by any federal healthcare program, we do not believe that our business will be subject to the federal Sunshine Act unless it is reimbursed in the future.

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

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

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

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

Foreign Corrupt Practices Act

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

International laws

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

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

U.S. healthcare reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of the Obalon Balloon System. By way of example, ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the medical device industry. The ACA, among other things, imposed a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions. The excise tax was suspended, effective January 1, 2016 and subsequently repealed, effective January 1, 2020.

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

EMPLOYEES

As of December 31, 2020, we had 2 employees, both of which are full-time. None of our employees are represented by a labor union or are parties to a collective bargaining agreement, and we believe that our employee relations are good.

FINANCIAL INFORMATION

We manage our operations and allocate resources as a single reporting segment. Financial information regarding our operations, assets and liabilities, including our net loss for the years ended December 31, 2020 and 2019 and our total assets as of December 31, 2020 and 2019, is included in our Consolidated Financial Statements in Item 8 of this Annual Report.

CORPORATE INFORMATION

We were incorporated under the laws of the State of Delaware on January 2, 2008. Our principal executive offices are located at 5421 Avenida Encinas, Suite F, Carlsbad, CA 92008, and our telephone number is (760) 607-5164. Our website addresses is http://www.obalon.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this prospectus. We have included our website address solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

AVAILABLE INFORMATION

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information with the Securities and Exchange Commission, or SEC. Our filings with the SEC are available free of charge on the SEC's website at *www.sec.gov* and on the "Investor Information" section of our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also read and copy, at SEC prescribed rates, any document we file with the SEC at the SEC's Public Reference Room located at 100 F Street, N.E., Washington D.C. 20549. You can call the SEC at 1-800-SEC-0330 to obtain information on the operation of the Public Reference Room.

ITEM 1A. Risk Factors

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Annual Report on Form 10-K, our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. The market price of our common stock would likely decline, and you could lose all or part of your investment.

RISKS RELATED TO THE MERGER

The conditions under the Merger Agreement may not be satisfied or waived and there can be no assurance that the Merger will be consummated.

On January 19, 2021, we entered into the Merger Agreement with ReShape Lifesciences Inc. and Optimus Merger Sub, Inc., a wholly owned subsidiary of the Company, pursuant to which, Merger Sub will merge with and into ReShape, with ReShape becoming a wholly owned subsidiary of Obalon. Consummation of the proposed Merger requires that a number of conditions must be satisfied or waived (to the extent permitted by applicable law). Those conditions include, among others:

- approval of the contemplated transactions by Obalon stockholders and ReShape stockholders
- the absence of any adverse law or order promulgated, entered, enforced, enacted, or issued by any government entity that prohibits, restrains, or makes illegal the consummation of the Merger or the other transactions contemplated by the Merger Agreement;
- the effectiveness of a registration statement on Form S-4, which shall include this joint proxy statement/prospectus, under the Securities Act and the absence of any stop order issued by the SEC suspending the use of such registration statement;
- Nasdaq's approval of the continued listing of our common stock on the Nasdaq Capital Market;
- subject to certain materiality exceptions, the accuracy of certain representations and warranties of each of us and ReShape contained in the Merger Agreement and the compliance by each party with the covenants contained in the Merger Agreement; and
- the absence of a material adverse effect with respect to us and ReShape.

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

Although an application will be filed for the continued listing of our common stock on The Nasdaq Capital Market in connection with the Merger, there can be no assurance that our common stock will be so listed or, if listed, that the Combined Company following the Merger will be able to comply with the continued listing standards.

An application to list our common stock on The Nasdaq Capital Market upon consummation of the Merger has been filed as required by The Nasdaq Capital Market. As part of the listing process, the Combined Company will be required to evidence that it meets the initial listing requirements rather than the continued listing requirements because the Merger will result in a change of control of the Company. In certain respects, the initial listing requirements are more onerous than the continued listing requirements, such as the minimum bid price of the common stock of $4.00 per share for initial listing compared to $1.00 per share for continued listing. There can be no assurance that the Combined Company will be able to meet the initial listing standards of The Nasdaq Capital Market or any other exchange or, if its stock is listed, that the Combined Company will be able to maintain our listing.

Nasdaq's approval of the listing application is a condition to the closing of the Merger and while we and ReShape can each terminate the Merger Agreement if the condition is not satisfied (in which case, a $1 million termination fee may be payable to us by ReShape), we and ReShape can also each choose to waive the condition and consummate the Merger without Nasdaq's approval of the listing application. In the event we and ReShape waive that condition and consummate the Merger without Nasdaq's approval of the listing application, the Combined Company would not be listed on the Nasdaq Capital Market.

In addition, if after listing, The Nasdaq Capital Market delists our common stock from trading on its exchange for failure to meet the continued listing standards, the Combined Company and its stockholders, which will include our current stockholders, could face significant material adverse consequences including:

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

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

The announcement and pendency of the Merger could disrupt our business, in any of the following ways, among others:

- the attention of our management may be directed toward completion of the Merger, integration planning and transaction-related considerations and may be diverted from our day-to-day business operations and, following the completion of the Merger, the attention of the Combined Company's management may also be diverted to such matters;
- vendors, suppliers, business partners or others may seek to modify or terminate their business relationship with us or the Combined Company following completion of the Merger;
- We, or the Combined Company following completion of the Merger, and our respective directors could become subject to lawsuits relating to the Merger; and
- We may experience negative reactions from their stockholders and the medical community, among others.

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

Failure to consummate the Merger could negatively impact our future stock price, operations and financial results.

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

- a decline in the market prices of our common stock to the extent that their current market prices reflect a market assumption that the Merger will be consummated and will be beneficial to the value of our business after the Closing Date;
- having to pay certain costs related to the proposed Merger, such as legal, accounting, financial advisory, printing and mailing fees, which must be paid regardless of whether the Merger is consummated;
- addressing the consequences of operational decisions made since the signing of the Merger Agreement, including because of restrictions on our operations imposed by the terms of the Merger Agreement and decisions to delay or defer capital expenditures;
- returning the focus of management and personnel to operating the Company, as applicable, on a standalone basis, without any of the benefits expected to have been provided by the consummation of the Merger; and

- negative reactions from their respective stockholders, suppliers, employees, patients enrolled in our studies and the medical community.

If the Merger is consummated, the composition of the board of directors and management of the Combined Company will be comprised of the current board of directors and management of ReShape and our current stockholders will not have a majority ownership and voting interest in the Combined Company, which may affect the strategy and operations of the Combined Company.

Pursuant to the Merger Agreement, following the consummation of the Merger, the board of directors of the Combined Company will consist of the five current members of the board of directors of ReShape: Dan W. Gladney, Barton P. Bandy, Arda M. Minocherhomjee, Ph.D., Lori C. McDougal and Gary D. Blackford. Mr. Gladney will serve as the chair and Mr. Blackford will serve as lead director of the board of directors.

None of our current directors, officers or employees are expected to continue with the Combined Company.

This composition of the Combined Board may affect the Combined Company's business strategy and operating decisions following the consummation of the Merger, as compared to our board of directors prior to the Merger. If the Combined Company reestablishes commercial operations for the Obalon Balloon System, it will not be able to rely on the experience of our current board of directors, management or employees.

In addition, immediately following completion of the Merger and the issuance of our common stock to the ReShape stockholders at the Effective Time, our current stockholders in the aggregate will not have a majority ownership and voting interest in the Combined Company, which may result in our stockholders having less influence on the Combined Company's management and policies. Immediately following completion of the Merger, our stockholders and ReShape's stockholders are expected to own 49% and 51%, respectively, of the Combined Company's outstanding shares. As a result, our current stockholders may have less influence on the Combined Company's management and policies than they currently have.

RISKS RELATED TO OUR BUSINESS

We have suspended or terminated essentially all of our commercial efforts, shut down our manufacturing operations and terminated nearly all of our employees, and we cannot assure you when, if ever, these efforts will recommence.

Our commercial operations expose us to risks associated with public health crises and outbreaks of epidemic, pandemic, or contagious diseases, such as the current outbreak of a novel strain of coronavirus (COVID-19). To date, COVID-19 has had, and is expected to continue to have, an adverse impact on our operations, including our product sales, manufacturing, supply chains, and our expenses, including as a result of preventive and precautionary measures that we, other businesses, and governments are taking. Largely as a result of the COVID-19 crisis, we have permanently closed our two Obalon-branded or managed retail weight loss centers, suspended future expansion plans for new retail centers, stopped shipping product to all U.S. customers, terminated our agreement with our only international distributor, and terminated our sales and marketing organizations. We have also shut down our manufacturing operations, including terminating all manufacturing and related support personnel. During fiscal year 2020, we terminated all but two essential employees. These terminations included key long-time senior executives and other functional personnel with deep knowledge and expertise important to our business that has been acquired and developed over many years. We do not expect to restart any of our operations unless we are able to complete the Merger with ReShape. We cannot assure you when, if ever, we will achieve any of these objectives and we do not expect to generate any revenue unless and until we can restart.

There are many uncertainties regarding COVID-19, including governmental and public health responses and the unknown duration and extent of economic disruption. Due to the uncertainty surrounding COVID-19, we do not currently plan to re-open our retail treatment centers, re-initiate our retail treatment center expansion plans, restart manufacturing operations or to ship orders to U.S. customers or our former international distributor. Despite our efforts to manage and remedy these impacts on us, their ultimate impact also depends on factors beyond our knowledge or control, including the duration and severity of the COVID-19 outbreak as well as third-party actions taken to contain its spread and mitigate its public health effects. However, based on the current state of the pandemic in the United States and abroad, the disease has already disrupted our operations and had a material adverse effect on our business, results of

operations, financial condition, cash flows and stock price, as well heightened many of the risks described elsewhere in the "Risk Factors" section of this Annual Report on Form 10-K.

If we are unable to complete the Merger with ReShape and in the alternative unable to secure additional financing on favorable terms, or at all, we could be forced to liquidate all or some of our assets or seek bankruptcy protection to protect stakeholder value.

Given the changes during fiscal year 2020 to drastically reduce our organizational structure and eliminate our commercial operations, we anticipate that our cash and cash equivalents as of December 31, 2020 are sufficient to fund our operations beyond March 2022. If we are not able to raise capital to meet our needs, we will not be able to support any ongoing operations and may not be able to settle all of our liabilities. We have actively reviewed financial and strategic alternatives, including debt and equity financing, whole or partial sale of the company and a reverse merger in order to meet our capital needs and financial obligations, and increase stockholder value. If the Merger with ReShape is not completed, we may not be able to identify a viable alternative for capital raising and adequate funding to operate our business as a standalone company may not be available to us on acceptable terms, or at all.

In February 2020, we implemented a new purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Pursuant to the new purchase agreement with Lincoln Park, or the Lincoln Park Purchase Agreement, Lincoln Park has committed to purchase up to $15.0 million of our common stock from time to time over a 36-month period. The number of shares we may sell to Lincoln Park on any single business day in a Regular Purchase is 150,000, but that amount may be increased to up to 250,000 shares of our common stock, depending on the market price of our common stock at the time of sale and subject to a maximum limit of $1,000,000 per Regular Purchase. Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $15.0 million over the term of the Lincoln Park Purchase Agreement. In addition, under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding under the Lincoln Park Purchase Agreement unless we obtain stockholder approval or an exception pursuant to the rules of the Nasdaq Capital Market is obtained to issue more than 19.99%. This limitation will not apply in certain limited circumstances as set out in the Lincoln Park Purchase Agreement. We have not sold any shares to Lincoln Park in fiscal year 2020 under the current Purchase Agreement. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Capital Market. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Park's beneficial ownership exceeding 9.99% of the then outstanding shares of our common stock. Given the limitations under this arrangement, we do not believe it is adequate to provide sufficient funds for us to continue as a standalone company.

Even if we are able to raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders is likely to be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect existing stockholders' rights. Moreover, debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business.

If we do not complete the Merger with ReShape and are unable to obtain sufficient funds on acceptable terms or in a timely manner we will be forced to take additional actions, including attempting to sell all or portions of our business, liquidating all or some of our assets or seeking bankruptcy protection.

We have ceased our efforts to seek third-party reimbursement and are focused primarily on the successful close of the Merger with ReShape. If the Merger does not close and we are able to continue to operate as a standalone Company, our strategy to attain coverage and reimbursement by third-party payors may not be successful and will subject us to new risks, some of which we may not yet have identified.

During fiscal year 2020, we transitioned our business to develop a strategy to obtain coverage and reimbursement from third-party payors, which we believe could address one of the largest barriers to patient and physician adoption of the Obalon Balloon System. Historically, we utilized both a direct to physician model and a Company-managed Obalon-

branded retail treatment center strategy. Both of these commercial strategies utilized a patient cash-pay model, with varying degrees of success. Since entering into the Merger Agreement with ReShape, we have suspended our efforts to obtain coverage and reimbursement from third-party payors. The Merger is subject to a number of closing conditions and, if one of more of those conditions are not satisfied or waived, the Merger may not close and we would have to continue as a standalone company. As a standalone Company, we may not be able to restart commercial operations, renew our efforts to seek third-party reimbursement or determine and launch a different commercial strategy. Further, if we renew these efforts in the future, we cannot assure you that this new strategy will be successful nor which delivery model to the patient will be utilized in the future should we be able to obtain coverage and reimbursement from third-party payors.

Payors may refuse to provide coverage and reimbursement or change their coverage and reimbursement policies for intragastric balloon products as a category and/or for other obesity treatments and procedures, and these changes could negatively impact our business. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may 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 applied consistently or obtained in the first instance.

Completion of clinical trials necessary to support coverage and reimbursement could take several years or more. We cannot provide any assurance that we will successfully, or in a timely manner, enroll clinical trials, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by third-party payors as sufficient to support coverage and reimbursement. Successful results of predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, one or more third-party payors may disagree with our analyses and interpretation of the data from any clinical trial we undertake, or may find the clinical trial design, conduct, monitoring, or results unreliable or inadequate to support coverage and reimbursement. If we are unable to develop the clinical support needed to establish coverage and reimbursement, we may be unable to sell our products.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Even if we are successful in obtaining coverage from third-party payors for the Obalon Balloon System or procedures using the product, physicians may not purchase the Obalon Balloon System if they do not receive sufficient reimbursement from these payors for the cost of the product or procedures using our product. If government and other third-party payors do not provide coverage or adequate reimbursement levels for the Obalon Balloon System or procedures using the product, the demand for the Obalon Balloon System will not increase and/or create additional pricing pressure for us, either of which could adversely impact our business and financial condition.

If we are unable to reestablish commercial operations, including sales, marketing, manufacturing and distribution capabilities, whether after the completion of the Merger with ReShape, on our own or in collaboration with third parties, we may not be successful in commercializing our products.

We terminated all of our commercial personnel and no longer have a functioning infrastructure for the sales, marketing, or distribution of any product, and the cost of reestablishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market our product, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

If the Merger with ReShape, is consummated, and the Combined Company reestablishes commercial operations for the Obalon Balloon System, it will not be able to rely on the experience of our current board of directors or management since all of the members of our board of directors and management will resign in connection with closing of the Merger.

There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to regain customer confidence or recover market share that may have been ceded to competitors or other intragastric balloon technology;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs;
- the inability to negotiate with payors regarding reimbursement for our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we choose to enter into and maintain collaborative relationships for such sales, marketing and distribution capabilities, we would be highly dependent upon the collaborator's strategic interest in our products, and that collaborator's ability to successfully market and sell the product. To the extent that we depend on third parties for marketing and distribution, any revenue we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our products and may not become profitable. We may be competing with many companies that have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these companies.

We have received funding under the Coronavirus Aid, Relief and Economic Security (CARES) Act

On April 22, 2020, we executed a promissory note in favor of Silicon Valley Bank evidencing an unsecured loan in the aggregate principal amount of $430,047, which was made pursuant to the Paycheck Protection Program, or the PPP. The PPP was established under the CARES Act, which was enacted on March 27, 2020, and is administered by the U.S. Small Business Administration, or the SBA. All the funds under the loan were disbursed to us on April 23, 2020. The Company has used all proceeds from the loan to retain employees, maintain payroll and make lease and utility payments.

The promissory note provides for a fixed interest rate of one percent per year with a maturity date of April 22, 2022. Monthly principal and interest payments due on the loan are deferred for a six-month period beginning from the date of disbursement. The loan may be prepaid by the Company at any time prior to April 22, 2022 with no prepayment penalties or premiums.

Under the terms of the CARES Act, loan recipients can apply for and be granted forgiveness for all or a portion of the loans granted under the PPP. Such forgiveness will be subject to approval by the SBA and the lender and determined, subject to limitations, based on factors set forth in the CARES Act, including verification of the use of loan proceeds for payment of payroll costs and payments of mortgage interest, rent and utilities. In the event the loan, or any portion thereof, is forgiven, the amount forgiven is applied to outstanding principal. The terms of any forgiveness may also be subject to further regulations and guidelines that the SBA may adopt. If the loan is not forgiven, we will be required to repay the outstanding principal, along with accrued interest. We will carefully monitor all qualifying expenses and other requirements necessary to attain loan forgiveness; however, no assurance is provided that we will ultimately apply for or obtain forgiveness of the PPP loan in whole or in part.

The PPP loan application required us to certify, among other things, that the current economic uncertainty made the PPP loan request necessary to support our ongoing operations. On April 23, 2020, the SBA, in consultation with the Department of Treasury, issued new guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. We made the certification in good faith after analyzing our financial situation and access to capital and believe that we have satisfied all eligibility criteria for the PPP loan, but the SBA guidance and criteria is subject to interpretation and if we are found to be ineligible, we could be subject to significant penalties and required to repay the loan. If we become subject to

penalties or are not able to attain loan forgiveness, it could result in harm to our business, results of operation and financial condition. If, prior to the consummation of the Merger, we do not obtain a waiver from Silicon Valley Bank, the full amount of principal and interest outstanding under the PPP loan could become due and payable upon the consummation of the Merger.

We have limited operating experience and a history of net losses, and we recently discontinued all of our commercial operations.

We have a limited operating history upon which you can evaluate our business and we recently discontinued all of our commercial operations while we explore our ability to secure coverage and reimbursement for our products and other strategic alternatives. Prior to discontinuing our commercial operations, we had marketed our products only since January 2017 and our commercial sales experience has been limited. We have incurred significant losses in each period since our inception in 2008, with net losses of $12.3 million and $23.7 million during the fiscal year ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of approximately $184.8 million and had cash and cash equivalents of $3.9 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop, seek and obtain regulatory approval for our current and future generation Obalon Balloon System and sell our Obalon Balloon System in international and U.S. markets, and commercialize our Obalon Balloon System in the United States. Our consolidated financial statements as of and for the fiscal year ended December 31, 2020 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Pending the result of the Merger, if we are not able to raise additional capital in a timely manner, we will not be able to support or restart our commercial operations.

Our costs and expenses may increase significantly if we determine to pursue additional clinical trials that may be needed to secure reimbursement. If we secure reimbursement and return to commercial operations, we would expect our costs and expenses to increase substantially as we rebuild our sales and marketing and manufacturing capabilities. As a public company, we will continue to incur significant insurance, legal, accounting, compliance and other expenses, and we expect our losses to continue for the foreseeable future. Unless and until we return to commercial operations, we do not expect to generate any revenue. We cannot assure you when, if ever, we will generate revenue and, if we do, whether we will ever achieve profitability.

Our business is entirely dependent on sales of the Obalon Balloon System, which we are currently not manufacturing, marketing or selling.

All of our revenue to date was attributable to sales of our Obalon Balloon System including its component parts and accessories. In 2020, largely due to the COVID-19 crisis, we discontinued all of our commercial operations while we explore our ability to secure coverage and reimbursement for our products and other strategic alternatives. Even if we are able to secure reimbursement for the Obalon Balloon System and restart commercial operations, there are a number of factors that may contribute to our financial results, including:

- patient interest in and demand for our Obalon Balloon System;
- our ability to obtain adequate coverage and reimbursement for the Obalon Balloon System;
- positive or negative media coverage, or public, patient and/or physician perception, of our Obalon Balloon System, the procedures or products of our competitors, or our industry;
- any safety or efficacy concerns that arise through physician and patient experience with our Obalon Balloon System;

- any safety or efficacy concerns for the category of intragastric balloons, including liquid-filled balloons, as the FDA has issued four Letters to Health Care Providers warning them about the use of liquid-filled intragastric balloons citing potential risks, including death;
- our ability to service and maintain equipment such as the Obalon Navigation System;
- delays in, or failure of, product and component deliveries by our third-party suppliers and single-source suppliers;
- willingness of physicians to purchase the capital equipment required to place balloons using the Obalon Navigation System;
- difficulties in producing a sufficient quantity of our product to meet commercial demand due to shortages of component parts or due to issues in the manufacturing process;
- introduction of new procedures or products for treating patients who are obese or overweight that compete with our product;
- adverse changes in the economy that reduce patient demand for elective procedures; and
- favorable or unfavorable positions developed on intragastric balloons, or the Obalon Balloon System by professional medical associations, such as the American Society for Metabolic and Bariatric Surgery (ASMBS), the American Society for Gastrointestinal Endoscopy (ASGE), or other organizations with influence on physicians.

It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

Because we devote substantially all of our resources to our Obalon Balloon System and rely on our Obalon Balloon System as our sole source of revenue, any factors that negatively impact our product, or result in decreasing product sales, would materially and adversely affect our business, financial condition and results of operations.

We have historically maintained a high level of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges especially if we restart commercial operations and manufacturing in the future.

We are a vertically integrated manufacturer and insufficient demand for our products subjects us to risks. As a result of the need to maintain substantial levels of inventory due to single third-party sourcing and long lead-times to develop alternate third-party sources, we historically carried a high level of inventory for strategic materials. Due to the suspension of our business operations, we have ceased shipping product to U.S. and international customers, closed our Obalon-branded retail treatment centers and halted expansion of our retail treatment center model. We performed an impairment analysis and recognized $1.3 million in asset impairment charges during the second quarter of 2020.

Physicians have been slow to adopt and use intragastric balloons, and adverse events or other negative developments involving other companies' intragastric balloons or other obesity treatments may further slow patient adoption, which have negatively impacted our financial performance and strategic options and this could continue into the future.

Intragastric balloons represent a relatively new category of treatment for obese and overweight patients that is small, immature and not currently covered or reimbursed by third-party payors. We are currently aware of only one other intragastric balloon available for commercial sale in the United States, which was first commercially available in 2015. As a result, patient and physician awareness of intragastric balloons as a treatment option for obesity and weight management, and experience with intragastric balloons, is minimal. Prior to discontinuing our commercial operations, we experienced limited penetration of this market, and any future success will depend in large part on our ability to obtain coverage and reimbursement, to further develop the currently small and immature intragastric balloon market, educate physicians and patients, and to successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our Obalon Balloon System.

Additionally, because the market for intragastric balloons is new and developing and contains a limited number of market participants, our products could be negatively impacted by unfavorable market reactions to these other devices. If the use of these or future intragastric balloons results in serious adverse device events, or SADEs, or such products are subject to malfunctions or misuse, patients may attribute such negative events to intragastric balloons generally, which may adversely affect market adoption of our Obalon Balloon System. Since February 2017, the FDA has issued four separate letters to health care providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. We are aware of the filing of additional reports of serious adverse events, including deaths, associated with liquid-filled balloons since the issuance of the FDA safety alert letters. While the alerts were specific to liquid-filled intragastric balloons, not gas-filled intragastric balloons, these alerts could create negative perceptions of the entire category and slow down the acceptance of the Obalon Balloon System. Medical professional associations, such as ASMBS, have or may publish positions to their memberships which may be favorable or unfavorable toward the use of intragastric balloons, or the Obalon Balloon specifically. Additionally, if patients undergoing treatment with our Obalon Balloon System perceive the weight loss inadequate or adverse events too numerous or severe as compared with the treatment rates of alternative balloons or procedures, it will be difficult to demonstrate the value of our Obalon Balloon System to patients and physicians. As a result, demand for our Obalon Balloon System may decline or may not increase at the pace or to the levels we expect.

The efficacy of our Obalon Balloon System depends on patient compliance with a moderate intensity diet and behavior modification program. If patients are unwilling to make dietary and behavioral changes, patient outcomes may suffer which could negatively impact perception of our product in the marketplace both in the past and in the future.

Our Obalon Balloon System is approved as an adjunct to a moderate intensity diet and behavior modification program. As a result, in addition to undergoing the Obalon balloon procedure, patients will also need to modify their existing diet and level of physical activity in order to achieve their desired weight loss. If patients are unwilling to implement the appropriate dietary and behavioral changes, the amount of weight loss may be less than desired, leading to a negative perception of our product in the marketplace.

If patients are unable to successfully swallow the capsule or our balloon cannot otherwise be successfully deployed, patients may seek a refund or monetary damages in connection with the treatment.

Patients may be unable to successfully swallow the capsule that contains the Obalon balloon, potentially creating an economic disincentive for physicians to prescribe the Obalon Balloon System. In our SMART pivotal trial, 7.6% of the combined treatment and control group patients failed to swallow a capsule with the microcatheter attached despite success swallowing a placebo that did not have a catheter attached. We are experiencing similar rates in U.S. commercial usage. There have also been instances where balloon deployment was negatively impacted due to a leak in the microcatheter caused by the patient biting the catheter during placement and requiring endoscopic removal. There may be other reasons for unsuccessful placements of which we are not yet aware. If the balloon is not successfully placed for any reason, the patient may attempt to seek a refund or monetary damages for the treatment. Either scenario could cause a negative financial impact for us and could also create ill will with patients and physicians.

Additionally, patients may seek a refund or monetary damages from us due to Company-branded treatment center closures, inability to complete treatment, persistent side-effects resulting in early removal, and general discontent with outcomes.

Patients may experience serious injury related to the device or procedures as the result of the misuse or malfunction of, or design flaws in, our products, that could expose us to expensive litigation, divert management's attention and harm our reputation and business.

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, our business may suffer adverse consequences even in circumstances where a patient injury is caused by the actions of others, such as where a patient is injured due to the improper or negligent use of our products by a physician.

For instance, if the Obalon capsule does not reach a patient's stomach and there is a hardware or software malfunction such that it is inflated in the esophagus, the patient could experience a serious injury. A patient who experiences an esophageal inflation of the balloon would most likely require surgical intervention, and could die as a result of an esophageal inflation or as a result of complications from the subsequent intervention. Physicians may use the Obalon Navigation System to track the location of the balloon prior to inflation. Failure of the sensor to function or the Obalon Navigation System to dynamically track the capsule could result in serious injury if the Obalon balloon is inflated in another portion of the body, such as the esophagus. Perforation of the esophagus at any time, including during removal, is also possible. Esophageal perforation leading to sepsis and death associated with the sepsis has been reported with use of our product. Serious injury could also occur if one or more of the balloons deflates and migrates into the lower intestine causing an obstruction. This can also lead to surgical removal of the device and associated complications including death. Failure of the Obalon Touch Inflation Dispenser to function could result in need for immediate endoscopic removal or patient injury. Balloon deflation and migration into the lower intestine requiring surgical removal has also been reported with use of our product. Perforation of the stomach is also possible and can lead to surgical removal of the device and associated complications including death. Perforation of the stomach requiring surgical repair has also been reported with use of our product. One or more balloons may get lodged in the pyloric channel which could lead to severe dehydration and be life threatening and/or require surgical procedures to remove. Failure to transit has been reported with use of our product and unscheduled endoscopy has been performed to remove the uninflated balloon. Aspiration during placement or removal is also a risk with intragastric balloons which could lead to pneumonia or other serious injury. Acute pancreatitis has been reported that may or may not be associated with the use of our product. While we have designed our products, and established instructions and protocols for physicians, to attempt to mitigate such risks, we cannot guarantee that adverse events will not occur again in the future. For example, physicians and/or patients have in the past failed, and may again in the future fail, to follow our instructions and protocols, and the safety systems we design into our products may not prevent all possible adverse events and injuries and/or our products may fail to function properly.

Our quality assurance testing programs may not be adequate to detect all defects, which may result in patient adverse events, interfere with customer satisfaction, reduce sales opportunities, harm our marketplace reputation, increase warranty repairs and/or harm our revenue and results of operations. Our inability to remedy a product defect could result in a product recall, temporary or permanent withdrawal of a product from a market, product liability suits, damage to our reputation or our brand, inventory replacement costs or product reengineering expenses, any of which could have a material impact on our business, results of operations and financial condition.

In the past we have employed, and in the future we may employ social media and call center activities as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable laws and regulations, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA, CMS and Federal Trade Commission. For example, adverse events, product

complaints, off-label usage by physicians, unapproved marketing or other unintended messages could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill.

We have limited experience manufacturing our Obalon Balloon System and Obalon Navigation System in commercial quantities and, if we restart manufacturing, we may experience production delays or issues in our manufacturing organization and be unable to meet current or future demand.

Prior to 2017, the majority of our product sales had been to a single international distributor in the Middle East. We first sold our products to physicians and institutions in the United States in 2017, and we anticipate the United States to be our primary market focus going forward. We have limited experience in manufacturing the current Obalon Balloon System and all its related components in commercial quantities. Moreover, we recently terminated our existing manufacturing capabilities, and if we determine to restart commercial operations, we will need to reestablish those capabilities, and likely improve them, in order to satisfy expected demand. We may find that we are unable to successfully manufacture our products in sufficient quantities, on a timely basis and with the expected quality. Any failure to meet the quality, quantity and timeliness expectations of our customers could negatively impact our results of operations.

We have had and may in the future continue to encounter production delays or shortfalls caused by many factors, including the following:

- the termination of our manufacturing organization and related support functions and/or ability to successfully rehire the necessary talent and capabilities;
- the timing and process needed to assimilate the changes necessary to enable our production processes to accommodate anticipated demand;
- shortages that we may experience in any of the key components or sub-assemblies that we obtain from third-party suppliers, especially as we have not placed any future orders from those supplies;
- production delays or stoppages caused by receiving components or supplies which do not meet our quality specifications;
- delays that we may experience in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;
- delays that we may experience in seeking FDA review and approval of PMA supplements required for certain changes in manufacturing facilities, methods or quality control procedures;
- our limited experience in complying with the FDA's Quality System Regulation, or the QSR, which sets forth good manufacturing practice requirements for medical devices and applies to the manufacture of the components of our Obalon Balloon System;
- our ability to attract, train, and retain qualified employees, who are in short supply, in order to increase our manufacturing output;
- our ability to design and validate processes to allow us to manufacture future generations of the Obalon Balloon System that meets or exceeds our quality specifications in an efficient, cost-effective manner;
- our ability to produce commercial product that meets or exceeds our manufacturing specifications and release criteria;
- production delays or stoppages caused by malfunction of production equipment and/or malfunction of the electrical, plumbing, ventilation, or cooling systems supporting our manufacturing facility; and
- production stoppages and/or product scrap caused by positive tests for objectionable organisms on our products.

We depend on third-party suppliers, including single source suppliers, to manufacture some of our components and sub-assemblies, which could make us vulnerable to supply shortages, interruptions in production and price fluctuations that could harm our business. We have not ordered from those suppliers in approximately one year and they may be unwilling or unable to reinitiate supply of key materials and components.

Historically, we manufactured our Obalon Balloon System and some of its components and sub-assemblies at our Carlsbad facility, and we relied on third-party suppliers for other components and sub-assemblies used in production. In some cases, these suppliers were single source suppliers. For example, we relied on single suppliers for the extruded film, swallowable capsule, molded silicone valve used to manufacture our Obalon balloons and the hydrophilic coating for our catheters. We also relied on additional single source suppliers for components of our Obalon Navigation balloons and console, including sensors. These components are critical to our current and future products and there are relatively few alternative sources of supply. We do not carry a significant inventory of these components and obtaining additional components may require significant lead-time. We have experienced and may continue to experience production challenges due to shortages of key components from suppliers.

Moreover, we have not placed any future orders with our suppliers and they could refuse to fill future orders in the event we restart manufacturing, they may lose the capabilities to produce for us or they may refuse to do business with us at all in the future. Identifying and qualifying additional or replacement suppliers for any of the components or sub-assemblies used in our products could involve significant time and cost and could delay our ability to restart production and, going forward, could adversely affect our ability to fill product orders, service and maintain equipment with customers. For example, given that our Obalon Balloon System is a PMA approved product, any replacement supplier will have to be assessed by us through audits and other verification and assessment tools and found capable of producing quality components that meet our approved specifications, and we may be required to notify or obtain approval from the FDA for a change in a supplier prior to our ability to use the components it provides. If we were unable to find a replacement supplier, it could result in significant delays as we would be unable to produce additional product until such replacement supplier had been identified and qualified. If an existing or replacement supplier proposes to change any component specifications or quality requirements, the change may require FDA approval of a PMA supplement. If a supplier changes a component without notifying us, that change could result in an undetected change being incorporated into the finished product. Once detected and investigated, if the change is found to potentially affect the safety or effectiveness of the product, we would have to take corrective and preventive action, including possibly recalling the product, which could be time-consuming and expensive, and could impair our ability to meet the demand of our customers and harm our business and reputation.

In addition, our reliance on third-party suppliers for current and future products subjects us to a number of risks that could impact our ability to manufacture our products, service and maintain equipment with customers and harm our business, including:

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- change in payment terms, requiring upfront payment;
- concern regarding our current financial position or delay in our payments to suppliers; especially our key suppliers for the Obalon Navigation System console and balloon components, could negatively impact suppliers' perception of the Company and result in delayed or canceled delivery of components;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- interruption of supply resulting from modifications to, or discontinuation of, a supplier’s operations;
- damage to suppliers' facilities could interrupt supply;

- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and state regulatory authorities;
- inability to ensure the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- delays in delivery by our suppliers due to changes in demand from us or their other customers;
- our suppliers could attempt to manufacture products for our competitors using our intellectual property; and
- decisions by suppliers to exit the medical device business or discontinue supplying us.

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to assure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements, or supply components in a timely manner. Any significant delay or interruption in the supply of components or sub-assemblies, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business and financial results.

Historically, all of our international revenue was derived from sales to a single distributor that accounted for a significant amount of our revenue.

Al Danah Medical Company W.L.L, or Al Danah, was the sole distributor of our Obalon Balloon System in the Middle East and our sole international customer. International sales to Al Danah represented 15.1% and 48.4% of our total revenue for the year ended December 31, 2020 and 2019, respectively. Bader Sultan & Bros. Co. W.L.L., or Bader, was previously the sole distributor of our prior generation Obalon balloon system in the Middle East and our sole international customer. The agreement with Bader was terminated in December 2019. In May 2020 we terminated the agreement with Al Danah and will not ship them product in the future. The significant reduction in international revenue in 2020 has had a significant impact on our financial performance. Currently, we do not have regulatory approval for our Obalon Navigation System and Obalon Touch Inflation Dispenser in the Middle East. However, there are certain countries in the Middle East that allow importation of medical device products with United States FDA approval or clearance to meet local regulatory standards, including Qatar.

If we were to restart commercial operations as a standalone company, we would not intend to devote significant additional resources in the near-term to market our Obalon Balloon System internationally, which will limit our potential revenue from our product.

Marketing our Obalon Balloon System outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our longer-term product development and regulatory strategy, we may expand into other select international markets, but we do not currently intend to devote significant additional

resources to market our Obalon Balloon System internationally. Our decision to market our product primarily in the United States in the near-term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our product internationally. We have not submitted to the Competent Authority for CE-marking of the Obalon Navigation System or Obalon Touch Inflation Dispenser. Furthermore, given recent changes to the CE-mark process, which requires additional filings, the CE Mark for the prior version of the Obalon balloon system will not be renewed in May 2020.

The medical device industry, and the market for weight loss and obesity in particular, is highly competitive. If our competitors are able to develop and market products that are safer, more effective, easier to use or more readily adopted by patients and physicians, our commercial opportunities will be reduced or eliminated.

The medical device industry generally, and the market for weight loss and obesity specifically, are highly competitive, subject to rapid change and significantly affected by new product introductions, results of clinical research, corporate combinations, actions by regulatory bodies, changes by public and private payers and other factors. Because of the market opportunity and the high growth potential of the non-surgical device market for weight loss and obesity, competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products.

In the United States, our product competes with a variety of pharmaceuticals, surgical procedures and devices for the treatment of obese and overweight people. Large competitors in the surgical segment for weight loss and obesity include Ethicon Inc. (subsidiary of Johnson & Johnson), Medtronic plc (formerly Covidien Ltd.), Apollo EndoSurgery, Inc., and ReShape LifeSciences (which acquired the LAP-BAND from Apollo Endosurgery, Inc. and currently sells that device worldwide). We are aware of only one FDA approved, commercially marketed liquid-filled balloon device for treating overweight people, the ORBERA Balloon by Apollo EndoSurgery. Outside of the United States, Allurion Technologies, Inc. has developed a swallowable, passable liquid-filled intragastric for which they are seeking U.S. regulatory approval. Spatz Medical has also developed a liquid-filled intragastric balloon that has been approved for sale in Latin America and Europe and is seeking regulatory approval in the U.S. Additionally, we are aware of numerous companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, any of which, if approved, could compete with us in the future.

At any time, these or other competitors may introduce new or alternative products that compete directly or indirectly with our products and services. They may also develop and patent products and processes earlier than we can or obtain regulatory clearance or approvals faster than us, which could impair our ability to develop and commercialize similar products or services. If clinical outcomes of procedures performed with our competitors' products are, or are perceived to be, superior to treatments performed with our products, sales of our products could be negatively affected and our business, results of operations and financial condition could suffer.

Many of our competitors have significantly greater financial and other resources than we do, as well as:

- well-established reputations and name recognition with key opinion leaders and physician networks;
- an established base of long-time customers with strong brand loyalty;
- products supported by long-term data;
- longer operating histories;
- significantly larger installed bases of equipment;
- greater existing market share in the obesity and weight management market;
- broader product offerings and established distribution channels;
- greater ability to cross-sell products;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives; and

- more experience in conducting research and development, manufacturing, performing clinical trials and obtaining regulatory approvals or clearances.

Competition with these companies could result in significant price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing and future products, which may cause our revenues to decline and harm our business.

We have dramatically reduced our senior management team to only two full time employees and we cannot assure you that we have or would be able to recruit sufficient resources to manage our current operations or restart commercialization in the future.

Our success as a standalone company largely depends upon the services of our executive management team, which has been reduced to two employees: Andy Rasdal, our President and CEO, and Nooshin Hussainy, our Chief Financial Officer. Our former President and CEO, William Plovanic resigned on June 19, 2020. Mr. Plovanic continues to serve as a member of the Board of Directors. Mark Brister, our Chief Technology Officer, and Amy VandenBerg, our Chief Clinical, Regulatory and Quality Officer, resigned on July 3, 2020 but continue to provide limited services on a consulting basis. Bob MacDonald, our Chief Retail Officer, resigned on March 13, 2020. We cannot assure you that the remaining executives will be sufficient to implement our current business plan. Additionally, we do not currently maintain key personnel life insurance policies on any of our employees. Moreover, if we are successful in securing reimbursement for our products, we will need to attract and retain additional executive officers and numerous highly qualified personnel. Competition for executive officers and skilled personnel is intense. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. If we are unable to attract and retain additional executive officers or other key employees it could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Diego area, are particularly focused on the value of the stock awards they receive in connection with their employment. As a result, the current market price of our common stock, in particular as it relates to exercise prices of our outstanding options, limits our ability to retain existing employees and makes it difficult to attract additional highly skilled employees. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials, and any failure of those parties to fulfill their obligations could increase costs and cause delays.

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to help facilitate the clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and to comply with applicable regulations and standards, commonly referred to as good clinical practices, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product properly and on time. While we will have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties

do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful to support product approval of a commercially viable product, or at all, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances or approvals that we need to commercialize our products and delay commercialization.

RISKS RELATED TO REGULATORY MATTERS

In the future, our Obalon Balloon System may be subject to product recalls that could harm our reputation and business.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects with the Obalon Balloon System and the Obalon Navigation System or deficiencies of other products in the intragastric balloon category. Recalls of our Obalon Balloon System would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations.

Depending on the corrective action we take to redress a device product's deficiencies or defects, the FDA may require us, or we may decide to, obtain new approvals, clearances, or other marketing authorizations for the device before we may market or distribute the corrected device. Seeking such authorizations may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, Form 483s, product seizure, injunctions, administrative penalties, or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary recalls or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our stock price.

If patients using our products experience adverse events or other undesirable side effects, regulatory authorities could withdraw or modify our commercial approvals, which would adversely affect our reputation and commercial prospects and/or result in other significant negative consequences.

Undesirable side effects caused by our Obalon Balloon System could cause us, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials, and could result in more restrictive labeling than originally required, cause the FDA or other regulatory authorities to subsequently withdraw or modify our PMA or other commercial approvals, or result in the delay or denial of regulatory approval by other notified bodies. For example, in the 1980s and early 1990s, the FDA required additional post-market safety and efficacy data collection and analysis on an earlier version of an intragastric balloon after patients suffered severe side effects and complications with the device, which ultimately resulted in the withdrawal of the PMA approval.

Since February 2017, the FDA has issued four separate letters (known as Safety Alerts) to health care providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. While the Safety Alerts were specific to liquid-filled intragastric balloons and not gas-filled intragastric balloons, these adverse events could result in the FDA taking action against the entire intragastric balloon category which may cause negative consequences for us including requiring additional warnings, precautions and/or contraindications in the labeling than originally required, delaying or denying approval of our future products, or possible review or withdrawal of our current approval.

If we are unable to demonstrate that any adverse events are not related to our product, the FDA or other regulatory authorities could order us to cease further development of, require more restrictive indications for use and/or additional

warnings, precautions and/or contraindications in the labeling than originally required, or delay or deny approval of any of our future products. Even if we are able to do so, such event could affect patient recruitment or the ability of enrolled patients to complete a clinical trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our products, the commercial prospects of such product may be harmed and our ability to generate product revenues from our product may be delayed or eliminated. Any of these occurrences may harm our ability to develop other products, and may harm our business, financial condition and prospects significantly.

In addition, we or others may later identify undesirable side effects caused by the product (or any other similar product), resulting in potentially significant consequences, including:

- the FDA or European notified bodies may withdraw or limit their approval of the product;
- the FDA or European notified bodies may require the addition of labeling statements, such as a contraindication;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may be required to correct or remove the products from the marketplace or decide to conduct a voluntary recall;
- we may decide to alert physicians through customer notifications;
- the FDA may use publicity such as a press release to alert our customers and the public of the issue;
- physicians and patients may be dissatisfied, seek refunds and refuse to use our products;
- we could be sued and held liable for injury caused to individuals using our product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our Obalon Balloon System and could substantially increase the costs of commercializing our product and significantly impact our ability to successfully commercialize our product and generate product sales.

Even though we have received FDA approval of our PMA application to commercially market the Obalon balloon system in the United States, we will continue to be subject to extensive FDA regulatory oversight.

Our Obalon Balloon System, Obalon Navigation System, and Obalon Touch Inflation Dispenser are medical devices that are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. We will be required to timely file various reports with the FDA, including reports required by the

medical device reporting regulations, or MDRs, that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

We rely on our U.S. physician customers and international distributors for timely reporting of any adverse events or product malfunctions that occur, which may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. Notification by our U.S. physician customers and our international distributor on a timely basis or at all of such events could result in product liability or regulatory enforcement actions, both of which could harm our business.

In addition, as a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. For example, as part of our PMA

approval, we are required to conduct a post-approval study at up to 16 sites in the United States to evaluate the safety and efficacy of our Obalon Balloon System in approximately 200 subjects over a twelve-month period, consisting of six months of treatment with the Obalon Balloon System followed by six months of observation after balloon removal. We began patient enrollment in the post approval study in the second quarter of 2018 and in April 2019 we notified the FDA that we had temporarily paused active new patient enrollment to conserve cash resources and ensure we could meet future financial obligations to physicians and patients. We have subsequently notified the FDA in July 2019 that we restarted enrollment and as of March 31, 2020 we enrolled approximately 200 patients, which we believe represents full enrollment, and we would expect to complete follow-up on these patients in 2021. As part of our PMA-S approval of the Obalon Navigation System, we are required to conduct a post-approval study at up to 40 sites in the United States to evaluate the safety and efficacy of our Obalon Navigation System for approximately 4,000 balloon placements, as it relates to the safety and efficacy of acute balloon placement including deployment, but not long-term results such as weight loss. We began enrollment of the Obalon Navigation System post-approval study in December 2019. In the first quarter of 2020, we enrolled 32 patients with 81 balloon administrations in the Obalon Navigation System post-approval study. We have notified the FDA that we have temporarily paused active new patient enrollment as a result of ceasing to ship new product to commercial customers and the closure of the Obalon-branded retail treatment centers. We intend to keep this study paused until we secure a pathway to a product reimbursement trial where we will evaluate how to collect the data required to support this study in conjunction with the data required of a third-party payor or other wise begin commercializing again. This study will have to be resumed in connection with the resumption of manufacturing and distributing the Obalon Balloon System. The product labeling for any product subject to a post-approval study must be updated and submitted in a PMA supplement as results, including any adverse event data, from the post-approval study data become available. Failure to conduct post-approval studies in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would materially harm our business. Moreover, if post-approval studies of our products reveal unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures, and we are required to modify the approved labeling for our products to include such adverse findings, such labeling modifications could have a materially adverse effect on our ability to market and sell the affected products.

If we initiate a correction or removal for one of our devices, issue a safety alert, or undertake a field action or recall to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall, which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases, or administrative or judicial enforcement actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

Since February 2017, the FDA has issued four separate letters to health care providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. The letters were specific to liquid-filled intragastric balloons and not gas-filled intragastric balloons. However, these adverse events associated with liquid-filled intragastric balloons could result in the FDA taking action against the entire gastric balloon category, which may cause negative consequences for us including requiring additional warnings, precautions and/or contraindications in the labeling than originally required, delaying or denying approval of our future products, or possible review or withdrawal of our current approval.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are false, misleading, not substantiated or not permissible, we may be subject to enforcement actions, including Warning Letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

Additionally, the medical device industry's relationship with physicians is under increasing scrutiny by the Health and Human Services Office of Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our

relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies, could significantly harm our business.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, Form 483s, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for 510(k) clearance or PMA approvals or foreign regulatory approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current administration may impact our business and industry. The current administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Material modifications to our Obalon Balloon System and Obalon Navigation System may require new premarket approvals and may require us to recall or cease marketing our Obalon Balloon System until approvals are obtained.

Once a medical device is approved, a manufacturer must notify the FDA of any modifications to the device. Any modification to a device that has received FDA approval that affects its safety or effectiveness requires approval from the FDA pursuant to a PMA supplement. An applicant may make a change in a device approved through a PMA without

submitting a PMA supplement if the change does not affect the safety and effectiveness of the device and the change is reported to FDA in a post-approval periodic report required as a condition of approval. We may not be able to obtain additional premarket approvals for new products or obtain approval of PMA supplements for modifications to, or additional indications for, our Obalon Balloon System in a timely fashion, or at all. Delays in obtaining required future approvals would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. If we make additional modifications in the future that we believe do not or will not require additional approvals and the FDA disagrees and requires new approvals for the modifications, we may be required to recall and to stop selling or marketing our Obalon Balloon System as modified, which could harm our operating results and require us to redesign our Obalon Balloon System and Obalon Navigation System. In these circumstances, we may be subject to significant enforcement actions.

If we or our suppliers fail to comply with the FDA and international quality system requirements, our manufacturing operations could be delayed or shut down and sales of our Obalon Balloon System could suffer.

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, inspection, complaint handling, record keeping, management review, labeling, packaging, sterilization, storage and shipping of our Obalon Balloon System. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive record keeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we are found to not be in compliance at the conclusion of an FDA QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, issuance of a Warning Letter, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenues to decline.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA numerous times, the most recent of which occurred in November 2017, which resulted in no observations. Although we believe our manufacturing facilities and those of our critical component suppliers are in compliance with the QSR requirements, we can provide no assurance that we will continue to remain in compliance with the QSR. If our manufacturing facilities or those of any of our component suppliers are found to be in violation of applicable laws and regulations, or we or our suppliers have significant noncompliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, and Form 483s;
- fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for clearance or approval of new products or modified products;
- withdrawing clearances or approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility, we may be unable to produce our Obalon Balloon System, which would materially harm our business.

Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the International Organization for Standardization. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. If we fail to adequately comply with any of these standards, a foreign regulatory body may take adverse actions similar to those within the power of the FDA. Any such action may harm our reputation and could have an adverse effect on our business, results of operations and financial condition.

We also have an ISO 13485:2003 Quality System Certificate through British Standards Institution, or BSI, that is required to support our CE mark. We have been audited at least annually and are subject to unannounced audits by BSI which could result in major nonconformances. Major nonconformances could result in the suspension or revocation of our ISO Certificate, which would disrupt distribution in the European Union and other countries that require certificated Quality Systems.

Our success depends on our ability to obtain FDA approval or other regulatory approvals for our future products and product improvements.

The successful commercialization of the Obalon Balloon System is dependent on the successful development and commercialization of future devices intended to improve the safety, efficacy, ease-of-use or cost of the Obalon Balloon System. A product we have under development includes a longer-term duration balloon, intended to remain in the stomach for up to twelve months.

We cannot assure you that this or other devices or improvements we develop will receive regulatory approval in the United States or in other regulatory jurisdictions outside the United States, including the Middle East or CE-Mark. A number of companies in the medical device field have suffered significant setbacks during evaluation due to lack of efficacy or unacceptable safety issues, notwithstanding promising preliminary results. Our failure to receive regulatory approval in jurisdictions outside the United States, in a timely manner or at all, could harm our financial results and ability to become profitable. Even if we obtain regulatory approval for one or more of these new products, the terms of such regulatory approval may limit our ability to successfully market the approved product.

The FDA and other regulatory agencies actively enforce the laws and regulations governing the development, approval and commercialization of medical devices. If we are found to have failed to comply with these laws and regulations, we may become subject to significant liability.

The Obalon Balloon System is classified by the FDA as a Class III medical device. As a result, we are subject to extensive government regulation in the United States by the FDA and state regulatory authorities. We are also subject to foreign regulatory authorities in the countries in which we currently and intend to conduct business. These regulations relate to, among other things, research and development, design, pre-clinical testing, clinical trials, manufacturing, packaging, storage, premarket approval, environmental controls, safety and efficacy, labeling, advertising, promotion, pricing, recordkeeping, reporting, import and export, post-approval studies and the sale and distribution of the Obalon Balloon System.

Further, the FDA and European regulatory authorities strictly regulate the indications for use and associated promotional safety and effectiveness claims, including comparative and superiority claims vis a vis competitors' products, that may be made about products, such as the Obalon Balloon System. In particular, a medical device may not be promoted for uses or indications that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. For example, we will not be able to promote or make claims for the Obalon Balloon System for the treatment of patients outside of the BMI ranges specifically approved by the FDA or other regulatory authorities. In the United States, we received FDA approval of the Obalon Balloon System for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40) who have failed to lose weight through diet and exercise. The Obalon Balloon System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be

removed six months after the first balloon is placed. Our pivotal trial inclusion and exclusion criteria included patients with a BMI of 30 to 40; thus, our approved labeling is limited to the same BMI range. We also will not be able to make comparative or superiority claims for the Obalon Balloon System versus other products without scientific data supporting or establishing those claims, including possibly data from head-to-head clinical trials if appropriate. Our CE mark label includes patients with a BMI of 27 or greater. As a part of our PMA approval, we are required to conduct a post-approval study at up to 16 sites in the United States to evaluate the safety and efficacy of our Obalon Balloon System over a twelve-month period, consisting of six months of treatment with the Obalon Balloon System followed by six months of observation after balloon removal. We began patient enrollment in the post-approval study in the second quarter of 2018 and in April 2019 we notified the FDA that we had temporarily paused active new patient enrollment to conserve cash resources and ensure we could meet future financial obligations to physicians and patients. We have subsequently notified the FDA in July 2019 that we restarted enrollment and as of December 31, 2020 we have completed enrollment and would expect to complete follow up on these patients in 2021. Failure to conduct post-approval studies in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would materially harm our business. As part of our PMA-S approval of the Obalon Navigation System, we are required to conduct a post-approval study of up to 40 sites in the United States to evaluate the safety and efficacy of our Obalon Navigation System as it relates to acute balloon placement including deployment. We began enrollment of the Obalon Navigation System post approval study in December 2019. We have notified the FDA that we have temporarily paused active new patient enrollment as a result of ceasing to ship new product to commercial customers and the closure of the Obalon-branded retail treatment centers. We intend to keep this study paused until we secure a pathway to a product reimbursement trial where we will evaluate how to collect the data required to support this study in conjunction with the data required of a third-party payor or otherwise begin commercializing again. This study will have to be resumed in connection with the resumption of manufacturing and distributing the Obalon Balloon System. The product labeling for any product subject to a post-approval study must be updated and submitted in a PMA supplement as results, including any adverse event data, from the post-approval study data become available. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies, obtaining results different than our pivotal trial results or failure to comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

Physicians may choose to prescribe such products to their patients in a manner that is inconsistent with the approved label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and/or enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed, curtailed or prohibited. If we cannot successfully manage the promotion of and training for our Obalon Balloon System, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and/or approved by

necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, and regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If we fail to obtain and maintain regulatory approval in foreign jurisdictions, our market opportunities will be limited.

In order to market our products in the European Union, the Middle East or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance or approval. Foreign regulatory approval processes include many of the risks associated with obtaining FDA clearance or approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance or approval does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration. We currently do not have any approvals for the Obalon Navigation System and Obalon Touch Inflation Dispenser outside the U.S., including the Middle East and CE-Mark. Furthermore, given recent changes to the CE-mark process which requires additional filings, the CE Mark for the prior version of the Obalon Balloon System were not renewed in May 2020 and we have not renewed our agreement with our notified body. However, there are certain countries in the Middle East that allow importation of medical device products with United States FDA approval or clearance to meet local regulatory standards, including Qatar.

If we fail to comply with healthcare regulations and fraud and abuse laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Although intragastric balloon products similar to our Obalon Balloon System are not currently reimbursed by U.S. federal healthcare programs (such as Medicare or Medicaid) or other third-party payors, any future reimbursement by third-party payors could expose our business to broadly applicable fraud and abuse and other healthcare laws and regulations that would regulate the business, including laws that would regulate financial arrangements and relationships through which we market, sell and distribute the Obalon Balloon System. Additionally, as a device manufacturer, we are still subject to certain healthcare fraud and abuse regulation, including those laws that apply to self-pay products, and enforcement by the federal government and the states in which we conduct our business.

Applicable and potentially applicable U.S. federal and state healthcare laws and regulations and their foreign equivalents, include, but are not limited to, the following:

- ***Anti-Kickback Laws.*** The federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare and Medicaid, unless the arrangement fits within one of several statutory exceptions or regulatory "safe harbors." Courts have interpreted the term "remuneration" broadly under the Anti-Kickback Statute to include anything of value, such as, for example, gifts, discounts, payments of cash and waivers of payments. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare

programs. Exclusion of a manufacturer would preclude any federal healthcare program from paying for the manufacturer's products. A person does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, kickback arrangements can provide the basis for an action under the False Claims Act, which is discussed in more detail below.

Government officials have recently increased enforcement efforts with respect to sales and marketing activities of pharmaceutical, medical device, and other healthcare companies, and they have brought cases against individuals and entities that allegedly offered unlawful inducements to potential or existing customers in an attempt to procure business. Settlements of these government cases have involved significant fines and penalties and, in some instances, criminal pleas.

In addition to the federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same exceptions or safe harbors. In some states, the restrictions imposed by anti-kickback laws are not limited to items and services paid for by government programs but, instead, apply with respect to all payors for healthcare items and services, including commercial health insurance companies.

- ***False Claims Laws.*** The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. A manufacturer can be held liable under false claims laws, even if it does not submit claims to the government, if it is found to have caused submission of false claims. For example, these laws may apply to a manufacturer that provides information regarding coverage, coding or reimbursement of its products to persons who bill third-party payers. In addition, a violation of the federal Anti-Kickback Statute is deemed to be a violation of the federal False Claims Act.

The federal False Claims Act also includes whistleblower provisions that allow private citizens to bring suit against an entity or individual on behalf of the United States and to recover a portion of any monetary recovery. Many of the recent, highly publicized settlements in the healthcare industry relating to sales and marketing practices have related to cases brought under the federal False Claims Act.

The majority of states also have adopted statutes or regulations similar to the federal laws, which apply to items and services reimbursed under Medicaid and other state programs. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

- ***Other Healthcare Fraud Laws.*** HIPAA includes criminal health care fraud provisions and related rules that prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing or covering up a material fact or making any material false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- ***Transparency Laws.*** There has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals and entities. For example, the Physician Payment Sunshine Act, imposes annual reporting requirements on certain manufacturers of drugs, medical devices, biologics and medical supplies with respect to payments and other transfers of value provided by them, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as with respect to certain ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information regarding all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on medical device manufacturers' marketing practices, require reporting of marketing

and pricing information, and require the tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities under certain circumstances.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. In addition, the dynamic healthcare regulatory compliance environment and the need to build and maintain robust systems to comply with different reporting and other legal requirements in multiple jurisdictions, increase the possibility that a healthcare company may fail to comply fully with one or more of these laws or regulations. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. If our operations are found to be in violation of any of the healthcare regulatory laws to which the business is subject, or any other laws that apply to the business, we may be subject to penalties, including potentially significant criminal and civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, additional compliance and reporting requirements, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If retail arrangements with physicians or customers are found to violate state laws prohibiting the corporate practice of medicine or fee splitting, our business, financial condition and our ability to operate in those states could be adversely impacted.

The practice of medicine is highly regulated, and any future operation of retail treatment centers, arrangements with physicians and interactions with retail customers will be subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Regulatory oversight includes, but is not limited to, the corporate practice of medicine, fee-splitting, regulation and registration of medical practices, clinics and facilities and management companies by state and local licensing boards or other agencies, licensure and scope of practice limitation for physicians and other healthcare professionals, advertising and consumer protection laws. Certain states have laws, rules and regulations which require that medical practices be owned by licensed physicians and that business entities which are not owned by licensed physicians refrain from providing, or holding themselves out as providers of, medical care. These laws generally prohibit the practice of medicine by lay entities or persons and are intended to prevent unlicensed persons or entities from interfering with or inappropriately influencing the physician's professional judgment. The specific restrictions with respect to enforcement of the corporate practice of medicine and fee-splitting laws varies from state to state. Such laws may make it difficult for us to establish or expand our operations into a state, as interpretive legal precedent and regulatory guidance varies by jurisdiction and is often sparse and not fully developed. A determination that we are in violation of applicable restrictions on the practice of medicine or fee-splitting in any jurisdiction in which we operate, could have a material adverse effect on us, particularly if we are unable to restructure our operations and arrangements to comply with the requirements of that jurisdiction, if we are required to restructure our operations and arrangements at a significant cost, or if we are subject to penalties or other adverse action.

If we or our affiliated physicians fail to comply with licensing and accreditation requirements applicable to our business, various governmental agencies may impose fines or preclude us from operating in certain states.

Federal, state, and local laws and policies impose various registration, accreditation, permit and/or licensing requirements on healthcare facilities and subject healthcare facilities to regulations ranging from the adequacy of medical care, to compliance with building codes and environmental protection laws. Additionally, physicians at our retail treatment centers, once operational, will also be subject to various state and federal regulations, including utilization of diagnostic tests and regarding prescribing medication and controlled substances. Delays or failures to obtain or maintain any required registrations, accreditations, permits and other licenses could adversely impact our ability to establish and operate our retail treatment centers.

Moreover, each state defines the scope of practice of physicians and other healthcare professionals through legislation and through their respective boards of medicine and we will need to comply with laws related to the physician supervision of services and scope of practice requirements. Activities that qualify as professional misconduct under state law may subject our personnel to sanctions, or may even result in loss of their license and could, possibly, subject us to sanctions as well. Some state boards of medicine impose reciprocal discipline, that is, if a physician is disciplined for having committed professional misconduct in one state where he or she is licensed, another state where he or she is also licensed may impose the same discipline even though the conduct occurred in another state. Our ability to operate profitably will depend, in part, upon our ability and the ability of our affiliated physicians and retail treatment centers to obtain and maintain all necessary licenses and other approvals and operate in compliance with applicable healthcare and other laws and regulations that evolve rapidly.

We are subject to data privacy and security laws and regulations governing our collection, use, disclosure, or storage of personally identifiable information, including personal health information, which may impose restrictions on us and our operations and subject us to penalties if we are unable to fully comply with such laws.

In order to provide our services and solutions, we routinely receive, process, transmit and store personally identifiable information, or PII, including personal health information, of individuals, as well as other financial, confidential and proprietary information belonging to our patients and third parties from which we obtain information. The receipt, maintenance, protection, use, transmission, disclosure and disposal of this information is regulated at the federal and state levels and we also have obligations with respect to this information pursuant to our contractual requirements with customers. These laws, rules and requirements are subject to frequent change. Compliance with new privacy and security laws, regulations and requirements may result in increased operating costs and may constrain or require us to alter our business model or operations.

HIPAA requires certain entities, referred to as “covered entities” (including most healthcare providers and health plans), to comply with established standards, including standards regarding the privacy and security of PHI. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their “business associates,” as such term is defined by HIPAA, which, among other things, obligate business associates to safeguard the covered entity’s PHI against improper use and disclosure. In addition, a business associate may face significant statutory and contractual liability if the business associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. We believe that our Company-owned or managed treatment centers were required to be HIPAA compliant; we do not believe our corporate offices are required to be HIPAA compliant, but are nevertheless committed to maintaining the security and privacy of patients’ health information. Violation of HIPAA could result in the imposition of civil or criminal penalties.

Numerous other federal, state and foreign laws may apply that restrict the use and protect the privacy and security of PII, including health information. These include state medical privacy laws, state social security number protection laws, state breach notification laws, and federal and state consumer protection laws. These various laws in many cases are not preempted by HIPAA and may be subject to varying interpretations by the courts and government agencies. For instance, In Europe, the GDPR, went into effect in May 2018 and imposes stringent data protection requirements for controllers and processors of personal data of persons within the EU. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Noncompliance or findings of noncompliance with applicable laws, regulations or requirements, or the occurrence of any privacy or security breach involving the misappropriation, loss or other unauthorized disclosure of sensitive personal

information, whether by us or by one of our third party service providers, could have a material adverse effect on our reputation and business, including, among other consequences, mandatory disclosure to the media, loss of existing or new patients, significant increases in the cost of managing and remediating privacy or security incidents and material fines, penalties and litigation awards, any of which could have a material adverse effect on our business, results of operations, and financial condition.

Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. We expect that there will continue to be new proposed laws, regulations and industry standards concerning privacy, data protection and information security in the United States, including the California Consumer Privacy Act, which went into effect January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. We cannot yet determine the impact such future laws, regulations and standards may have on our business. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, including health data, along with increased patient demands for enhanced data security infrastructure, could greatly increase our cost of providing our services, decrease demand for our services, reduce our revenue and/or subject us to additional liabilities.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

When operational, our research and development and manufacturing operations involve the use of hazardous substances and a greenhouse gas, and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances as well as the control and reduction of greenhouse gas emissions. In addition, such operations produce biological waste materials, such as human and animal tissue, and waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and, when operational, we disposed of the resultant waste materials in material compliance with environmental laws and regulations.

Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third part property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and results of operations.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect our Obalon Balloon System or our other products, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our commercial success will depend in part on our ability to protect our proprietary rights to the technologies and inventions used in, or embodied by, our products. We rely on a combination of patents, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. If we do not adequately protect our intellectual property rights and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

As of December 31, 2020, we held 29 issued U.S. patents and had 17 pending U.S. patent applications, as well as 22 international patents issued in regions including Europe, Mexico, Australia, Canada, Asia, and China and 59 pending international patent applications in regions including Australia, Canada, Europe, Asia, the Middle East and South America. Our issued patents expire between the years 2023 and 2038, and are directed to various features and combinations of features of the Obalon Balloon System technology, including the apparatus for connecting the balloon to an inflation catheter, the structure and composition of the balloon wall, and the composition of the initial fill gas.

As of December 31, 2020, we held two registered U.S. trademarks and 34 registered marks in Europe, the Middle East, Asia and Mexico. We have four pending U.S. trademark applications and no pending marks outside the United States.

Although an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability, and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect the Obalon Balloon System or any other products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our Obalon Balloon System before our relevant patents expire;
- we were the first to make the inventions shown in each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable;
- our commercial activities or products will not infringe the patents of others; or
- we will be in the financial position to defend our trademarks and patents.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of unpatented trade secrets, unpatented know-how and confidential and proprietary information, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will become known or be independently developed by a person that is not a party to such an agreement, including our competitors. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. If the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. For example, each of our patents and patent applications names one or more inventors having past or present affiliations with other institutions, and any of these institutions may assert an ownership claim. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as 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 infringe or be alleged to infringe the intellectual property rights of others, which may result in costly and time-consuming litigation, delay our product development efforts or prevent us from commercializing the Obalon Balloon System.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. The medical device industry is characterized by rapid technological change and extensive litigation regarding patent and other intellectual property rights. Our competitors and other industry participants, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. In addition, numerous third-party patents exist in the fields relating to our products. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

From time to time, third parties, including our competitors as well as other industry participants and/or non-practicing entities, may allege that the Obalon Balloon System or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. For example, during 2017, we settled intellectual property infringement claims made by two separate third parties. We believed the claims in both instances were meritless but settled the matters for a nominal cash payment and aggregate stock issuances of 17,500 shares, in exchange for which we received a general release of all claims. Additionally, we have received and may from time to time in the ordinary course of business continue to receive, letters from third parties advising us of third-party patents that may relate to our business. The letters typically do not explicitly seek any particular action or relief from us. Although these letters do not threaten legal action, these letters may be deemed to put us on notice that continued operation of our business might infringe the patent rights of such third parties. If we decide not to seek a license or do not otherwise obtain a license to such third-party patents, there can be no assurance that we will not become subject to infringement claims or will not be forced to initiate legal proceedings in order to dispose of such actual or potential infringement claims or to seek to invalidate the claims of such third-party patents.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and can have an uncertain outcome. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we determine it necessary or are required to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, an injunction may force us to stop or delay developing, manufacturing, selling or otherwise commercializing the Obalon Balloon System or our other products.

Intellectual property claims or litigation, regardless of merit, may be expensive and time-consuming to resolve, result in negative publicity, and divert our management's attention from our core business. In addition, if we are subject to intellectual property claims or litigation, we may:

- be subject to a protected period of uncertainty while the claims or litigation remain unresolved, which could adversely affect our ability to raise additional capital and otherwise adversely affect our business;

- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; and
- be required to redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible.

Furthermore, we also rely on our trademarks as one means to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

If any of the risks described above come to fruition, our business, results of operations, financial condition and prospects could be harmed.

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 for non-compliance with these requirements.

The U.S. Patent and Trademark Office, or US PTO, and various international, foreign governmental and foreign regional patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the US PTO and foreign patent agencies over the lifetime of the patent. There are situations in which noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. Our recent reduction in personnel to two full time employees may heighten this risk.

We may be involved in legal proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe our patents, trademarks or other intellectual property rights. Our ability to enforce our intellectual property rights depends on our ability to identify infringement. It may be difficult to identify infringers who do not advertise the components of their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product.

To counter infringement of our intellectual property rights, we have in the past been, and may in the future be, required to file infringement claims, which can be expensive and time-consuming. Even if successful, litigation to enforce our intellectual property rights could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Moreover, we may not have sufficient resources to bring these actions to a successful conclusion. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that a patent of ours is not infringed and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

Interference proceedings instituted by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to obtain a license under such rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or offer us a license at all. Our defense of interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Issued patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies.

If we initiated legal proceedings against a third party to enforce one of our patents, the defendant could counterclaim that the patent is invalid and/or unenforceable. Even if legal proceedings were not initiated, if we threatened a third party with a patent infringement lawsuit, the third party preemptively may sue us in a declaratory judgment action and seek to have our patent declared invalid or not infringed. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our products or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse impact on our business. An adverse result in any legal proceeding could put one or more of our patents at risk of being invalidated, found unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending intellectual property rights related to our products in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, the laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these problems were to occur, they could have a material adverse effect on our sales. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to medical devices, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be

commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may not adequately protect our rights or permit us to gain or keep any competitive advantage.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and is implementing the America Invents Act of 2011, a wide-ranging patent reform legislation. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the US PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

We may be subject to damages resulting from claims that we, our employees, consultants or third parties we engage to manufacture our products have wrongfully used, or disclosed, alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our current and former employees were previously employed at pharmaceutical companies and other medical device companies, including our potential competitors, in some cases until recently. We may be subject to claims that we, our current and former employees, consultants or third parties have inadvertently or otherwise used or disclosed alleged trade secrets or proprietary information of these former employers or competitors. In addition, we may be subject to claims that we caused a current or former employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction for our management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with third parties. A loss of key personnel or their work product could have an adverse effect on our business, results of operations and financial condition.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

On February 5, 2020, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15,000,000 of our common stock. The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement filed with the SEC on February 7, 2020. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park under the Purchase Agreement. Sales of our common stock, if any, to Lincoln Park under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more

difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

As of December 31, 2020, we have not sold any shares of our stock under the Purchase Agreement with Lincoln Park.

Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The public trading price for our common stock can be affected by a number of factors, including:

- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- whether we obtain coverage and reimbursement from third-party payors;
- quarterly variations in our or our competitors' results of operations;
- the results of our clinical trials;
- unanticipated or serious safety concerns related to the use of any of our products or competitive liquid-filled intragastric balloon products;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our products;
- regulatory or legal developments in the United States and other countries;
- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- performance of third parties on whom we rely, including for the manufacture of the components for our product, including their ability to comply with regulatory requirements;
- inability to obtain adequate supply of the components for any of our products, or inability to do so at acceptable prices;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation of our business;
- changes in the structure of healthcare payment systems;
- our commencement of, or involvement in, litigation;
- the announcement of new products or product enhancements by us or our competitors;
- competition from existing technologies and products or new technologies and products that may emerge;
- negative publicity, such as whistleblower complaints, about us or our products;
- developments, announcements or disputes related to patents or other proprietary rights issued to us or our competitors and to litigation;
- ability to meet Nasdaq minimum listing requirements; and

- developments in our industry.

In recent years, the stock markets generally and the stock prices of many companies in the medical device industry have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you purchased it and you may lose some or all of your investment.

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.

On August 6, 2020, we received two written notifications from the Nasdaq Listing Qualifications Staff that we were not in compliance with the Nasdaq Global Market's minimum bid price or market capitalization requirements for continued listing. Subsequently, we applied to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market. On December 10, 2020, Nasdaq notified us that our application transfer had been approved and the listing of our common stock on the Nasdaq Capital Market would be effective December 17, 2020. On December 16, 2020, we received a letter from Nasdaq indicating that we had regained compliance with Nasdaq's minimum bid price requirement. Upon the effective transfer of our common stock to the Nasdaq Capital Market on December 17, 2020, we regained compliance with the continued listing requirements of Nasdaq. We may not continue to be in compliance with the continued listing standards of Nasdaq and the Combined Company may not satisfy the initial listing standards of the Nasdaq Capital Market, as described in more detail above.

In the event that our common stock is delisted from the Nasdaq Global 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.

If securities or industry analysts do not publish research or reports about our business, publish negative reports about our business, or publish financial projections that we are unable to achieve, our share price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors, and their projections of our financial results. We do not have any control over these analysts and currently are not covered by any analysts. If analysts do cover us and downgrade our shares, change their opinion of our shares, change their financial projections, publish negative information about us or if we are unable to achieve their financial projections for us, our share price would likely decline. Several analysts that previously provided coverage of us have ceased to do so or have failed to regularly publish reports on us. If analysts fail to regularly publish reports on us, our visibility in the financial markets could decline even further, which could cause our share price or trading volume to decline. In addition, analysts may publish negative opinions concerning our company, business strategy or accounting policies, which could negatively impact our share price.

We are an emerging growth company, and intend to take advantage of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions described above. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Our executive officers, directors, principal stockholders and their affiliates have significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of December 31, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 21% of our outstanding capital stock. These stockholders may be able to influence the outcome of matters requiring stockholder approval. For example, these stockholders may be able to influence elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are subject to securities class action litigation.

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against us and certain of our executive officers in the United States District Court for the Southern District of California (Hustig v. Obalon Therapeutics, Inc., et al., Case No. 3:18-cv-00352-AJB-WVG, and Cook v. Obalon Therapeutics, Inc. et al., Case No. 3:18-cv-00407-CAB-RBB). On July 24, 2018, the court consolidated the lawsuits and appointed Inter-Local Pension Fund GCC/IBT as lead plaintiff. On October 5, 2018, plaintiffs filed an amended complaint. The amended complaint alleges that we and certain of our executive officers made false and misleading statements and failed to disclose material adverse facts about our business, operations, and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of the Company's initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation.

On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims.

On August 17, 2020, the parties submitted a final settlement agreement of the securities class action for court approval. A hearing on final settlement approval is scheduled for April 22, 2021. The settlement provides for a payment of $3.15 million to the plaintiffs, and provides that the defendants continue to deny the allegations and claims asserted by the plaintiffs, and are entering into the settlement solely to eliminate the burden and expense of further litigation. The Company expects that any amounts due as part of the settlement will be covered by the Company's insurance policies.

Such litigation could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition, reputation and cash flows. These factors may materially and adversely affect the market price of our common stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid any cash dividends on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Any return to stockholders will be limited to the appreciation of stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in the value of the stock. We cannot guarantee you that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

GENERAL RISK FACTORS

We may face product liability claims that could result in costly litigation and significant liabilities.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, marketing and selling of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. Claims may be made by patients, healthcare providers or others selling our products. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient.

We also may be subject to claims against us due to actions of others. We rely on physicians in connection with the placement and subsequent removal at the end of the six-month treatment period of our Obalon balloon. If these

physicians are not properly trained, are negligent, or willfully decide not to follow the instructions for use, the capabilities of our products may be diminished or the patient may suffer critical injury. We may face negative consequences from misconduct of physicians despite our best efforts to remediate situations arising from negligence of the physicians and may also face negative consequences from nonconformity of patient therapy. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and raw materials. This risk exists even if a device or product is cleared or approved for commercial sale by the FDA or other foreign regulators and manufactured in facilities registered with and regulated by the FDA or an applicable foreign regulatory authority.

Although we have, and intend to maintain, product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, or at all, and, if available, the coverages may not be adequate to protect us against any future product liability claims. In addition, we may seek additional insurance coverage; however, if we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will 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 result in significant costs and significant harm to our business.

For instance, patients could be harmed by the Obalon balloon if it is improperly inflated, inflated in the body other than in the stomach, not removed at the end of the six-month treatment period resulting in deflation, or if it deflates prematurely while in the body. Additionally, we do not sell our product sterilized, and it may be contaminated with forms of microorganisms prior to use. Any failure to follow the physician’s directions for use or the patient information guide, or any other defects, misuse or abuse associated with our product, could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot assure you that we will not face product liability suits.

In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our brand and business reputation;
- costly litigation;
- distraction of management’s attention from our primary business;
- loss of revenue;
- the inability to commercialize our product;
- decreased demand for our product;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants; and
- substantial monetary awards to patients or other claimants.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, or by refusing to sell to any physician not following the physicians' directions for use, any recall or market withdrawal of, or refusal to sell, our products may delay the supply of those products to our customers and may impact our reputation. We cannot assure you that we will be successful in initiating appropriate recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Any such recalls and market withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, results of operations and financial condition.

Since we began selling in the United States in January 2017, we have reported adverse events relating to patient injuries associated with use of the Obalon balloon in the FDA's MAUDE database. To-date, none of these adverse events have resulted in product liability claims against us.

If there are significant disruptions in our information technology systems including a cybersecurity breach, our business, financial condition and operating results could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory, product development tasks, quality assurance, clinical data, and customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or other catastrophic events. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Numerous and evolving cybersecurity threats pose potential risks to the security of our information technology systems, networks and products, as well as the confidentiality and integrity of our data. A security breach could impact the use of such products and the security of information stored therein.

The failure of our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory efforts and significantly increase our costs to recover or reproduce the data. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors or contractors. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue, regulatory actions or litigations. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could also incur liability. Any of these events could have a material adverse effect on our reputation, business, financial condition and results of operations.

Our costs could substantially increase if we experience a significant number of warranty claims.

We provide limited product warranties against manufacturing defects of our products. Our product warranty requires us to repair defects arising from product design and production processes, and, if necessary, replace defective components. The future costs associated with our warranty claims are uncertain due to our limited commercialization experience with our current generation Obalon Balloon System and lack of commercial experience with our Obalon Navigation System and Obalon Touch Inflation Dispenser. Thus far, we have not accrued a significant liability contingency for potential warranty claims.

We have instituted a swallow guarantee which may provide replacement of product for physicians and institutions when patients are unable to swallow a capsule. To qualify for a replacement of product, the physician must adhere by our policies and procedures. The swallow guarantee is limited to a certain number of swallow attempts per balloon placement, as well as other procedural and technical requirements. As a result of this program, our financial results or gross profit may be impacted.

If we experience warranty claims, including manufacturing defects as well as our swallow guarantee, in excess of our expectations, or if our repair and replacement costs associated with warranty claims increase significantly, we will incur liabilities for potential warranty claims that may be greater than we expect. An increase in the frequency of warranty claims or amount of warranty costs may harm our reputation and could have a material adverse effect on our business, results of operations and financial condition.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decrease.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting, however, while we remain an emerging growth company we will not be required to include the attestation report issued by our independent registered public accounting firm.

The process of designing and implementing our internal control over financial reporting, has been time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, are unable to comply with the requirements of Section 404 in a timely manner, are unable to assert that our internal control over financial reporting is effective or, once required, if our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third-party litigation as well as investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including directors' and officers' liability insurance, product liability insurance, business interruption insurance, medical malpractice, property insurance and workers' compensation insurance. The cost of maintaining directors' and officers' liability insurance and product liability insurance on implantable medical devices has increased substantially over the past few years and could continue to increase, due to general market trends, as part of an evaluation of our specific loss history and other factors. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become economically impractical or become unavailable to us due to exhaustion of the coverage or any other reason, we would be required to operate our business without indemnity from commercial insurance providers.

Our ability to utilize our net operating loss carryovers may be limited.

At December 31, 2020, we had federal and state net operating loss carryforwards, or NOLs, of approximately $157.4 million and $126.0 million, respectively. The federal and state tax loss carryforwards will begin expiring in 2028, unless previously utilized. The federal net operating loss carryover includes $69.2 million of net operating losses generated after 2017. Federal net operating losses generated in 2018 and beyond carryover indefinitely and may be generally be used to offset up to 80% of future taxable income. We also had federal and California research and development tax credit carryforwards totaling $3.4 million and $2.7 million respectively. The federal research and development tax credit carryforward will begin to expire in 2028 unless previously utilized. The California research tax credits do not expire.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50%

or more in the ownership positions of certain stockholders during a rolling three-year period. We have not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 have occurred.

If ownership changes within the meaning of IRC Section 382 have occurred, it could restrict our ability to use NOL carryforwards and research and development tax credits generated since inception. Limitations on our ability to use NOL carryforwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

Future sales and issuances of our common stock or other securities may result in significant dilution and could cause the price of our common stock to decline.

To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, including pursuant to the Purchase Agreement with Lincoln Park. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current board directors or management.

Provisions in our restated certificate of incorporation and our restated bylaws discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan, also known as a “poison pill”;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;

- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Moreover, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any of these provisions of our charter documents or Delaware law could, under certain circumstances, depress the market price of our common stock.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our restated certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, any action asserting a claim arising pursuant to any provision of the DGCL, our restated certificate of incorporation or our restated bylaws or any action asserting a claim that is governed by the internal affairs doctrine. Notwithstanding the foregoing, this provision will not apply to any claims arising under the

Securities Act or the Exchange Act, or any claim in which exclusive jurisdiction is vested in a court or forum other than the Court of Chancery or for which the Court of Chancery does not have subject matter jurisdiction. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our restated certificate of incorporation. This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our principal executive offices are located in a 20,200 square foot facility in Carlsbad, California. The term of the lease for our facility extends through March 2022. Our facility houses our research and development, sales, marketing, manufacturing, finance and administrative activities. We believe that our current facilities are adequate for our current needs.

ITEM 3. Legal Proceedings

From time to time, we are involved in legal proceedings in the ordinary course of business.

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against us and certain of our executive officers in the United States District Court for the Southern District of California (Hustig v. Obalon Therapeutics, Inc., et al., Case No. 3:18-cv-00352-AJB-WVG, and Cook v. Obalon Therapeutics, Inc. et al., Case No. 3:18-cv-00407-CAB-RBB). On July 24, 2018, the court consolidated the lawsuits and appointed Inter-Local Pension Fund GCC/IBT as lead plaintiff. On October 5, 2018, plaintiffs filed an amended complaint. The amended complaint alleges that we and certain of our executive officers made false and misleading statements and failed to disclose material adverse facts about our business, operations, and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of the Company's initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation. On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims. On August 17, 2020, the parties submitted a final settlement agreement of the securities class action for court approval. A hearing on final settlement approval is scheduled for April 22, 2021. The settlement provides for a payment of $3.15 million to the plaintiffs, and provides that the defendants continue to deny the allegations and claims asserted by the plaintiffs, and are entering into the settlement solely to eliminate the burden and expense of further litigation. The Company expects that any amounts due as part of the settlement will be covered by the Company's insurance policies.

On October 13, 2020, Gildred Development Company ("Gildred"), our landlord in Carlsbad, served us with an unlawful detainer action in the Superior Court of California, County of San Diego (Gildred Development Company v. Obalon Therapeutics, Inc., Case No. 37-2020-00035927-CU-UD-CTL). Gildred alleges that we owe more than $113,000 of unpaid rent and fees to Gildred and seeks damages for unpaid rent and continued occupancy of the premises. On November 18, 2020, Gildred filed an ex parte application for a writ of attachment or, in the alternative, a temporary protective order. The application was denied on November 24, 2020. On December 28, 2020, Gildred filed another application for a writ of attachment or, in the alternative, a temporary protective order. On January 22, 2021, the court granted Gildred's application for a writ of attachment. We have paid the amount of the writ in full, which was $338,000 and the parties resolved the claim. We are current on our rent obligations under the lease with Gildred.

ITEM 4. Mine Safety Disclosures

None.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock began trading on The Nasdaq Global Market on October 6, 2016 and was transferred to the Nasdaq Capital Market on December 17, 2020 and trades under the symbol "OBLN." Prior to October 6, 2016, there was no public market for our common stock.

Holders of Record

As of March 4, 2021, there were approximately 65 stockholders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

The information called for by this item is incorporated by reference to our definitive proxy statement for the 2021 Annual Meeting of Stockholders. See Part III, Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On October 5, 2016, our Registration Statement on Form S-1/A (File No. 333-213551) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to the IPO, we sold an aggregate of 5,000,000 shares of our common stock at a price of $15.00 per share which resulted in net proceeds to us of approximately $67.2 million, after deducting underwriting discounts and commissions of approximately $5.2 million, and estimated offering costs of approximately $2.6 million.

Through December 31, 2020, all of the net proceeds have been used primarily for the commercialization of our Obalon Balloon System, continued research and development efforts, working capital and other general corporate purposes.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. Selected Consolidated Financial Data

We have derived the following selected consolidated statement of operations data for the years ended December 31, 2020 and 2019 and the selected consolidated balance sheet data as of December 31, 2020 and 2019 from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We have derived the

following selected consolidated statement of operations data for the years ended December 31, 2018, 2017 and 2016 and the selected consolidated balance sheet data as of December 31, 2018, 2017 and 2016 from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. Please read the following selected financial data in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Year ended December 31,				
	2020	2019	2018	2017	2016
Consolidated statements of operations data:					
Revenue:					
Revenue	$ 1,588	$ 3,281	$ 9,101	9,914	—
Revenue, related party	—	—	—	—	3,393
Total revenue	1,588	3,281	9,101	9,914	3,393
Cost of revenue	1,004	2,950	5,423	4,829	2,809
Gross profit	584	331	3,678	5,085	584
Operating expenses:					
Research and development	2,450	6,893	10,697	10,647	9,872
Selling, general and administrative	8,776	16,668	29,946	28,829	10,217
Asset impairment and other charges	1,310	—	—	—	—
Total operating expenses	12,536	23,561	40,643	39,476	20,089
Loss from operations	(11,952)	(23,230)	(36,965)	(34,391)	(19,505)
Interest income (expense), net	29	(385)	(226)	(135)	(477)
Loss from change in fair value of warrant liability	—	—	—	—	(466)
Other expense, net	(411)	(61)	(189)	(239)	(19)
Net loss	(12,334)	(23,676)	(37,380)	(34,765)	(20,467)
Other comprehensive income (loss)	—	—	5	(4)	(1)
Net loss and comprehensive loss	$ (12,334)	$ (23,676)	$ (37,375)	$ (34,769)	$ (20,468)
Net loss per share, basic and diluted[1]	$ (1.59)	$ (5.03)	$ (19.64)	$ (20.80)	$ (4.85)
Weighted-average common shares outstanding, basic and diluted[1]	7,738,355	4,706,775	1,903,734	1,671,796	4,221,893

(1) See Note 4 to our audited financial statements appearing elsewhere in this Annual Report for an explanation of the method used to calculate the basic and diluted net loss per common share and the number of shares used in the computation of the per share amounts.

	As of December 31,				
	2020	2019	2018	2017	2016
Consolidated balance sheet data:					
Cash and cash equivalents and short-term investments	$ 3,905	$ 14,055	$ 23,735	$ 44,400	$ 75,475
Working capital	2,789	14,258	11,416	41,744	73,469
Total assets	10,617	20,393	30,386	53,101	78,778
Debt	430	—	9,930	9,922	9,881
Accumulated deficit	(184,764)	(172,430)	(148,754)	(111,374)	(76,609)
Total stockholders' equity (deficit)	4,665	15,849	13,107	35,113	64,305

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Special note regarding forward-looking statements" and "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

OVERVIEW

We are a vertically integrated medical device company focused on developing and commercializing innovative medical devices to treat people with obesity. Our current product offering is the Obalon Balloon System, the first and only U.S. Food and Drug Administration, or FDA, approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in patients with obesity. We believe the Obalon Balloon System offers patients and physicians benefits over prior weight loss devices including, but not limited to, clinically meaningful weight loss, a favorable safety profile, improved patient tolerability and comfort, progressive weight loss with durable results, simple and convenient placement, and potentially attractive economics.

The Obalon Balloon System is FDA approved for temporary use to facilitate weight loss in adults with obesity having a body mass index, or BMI, of 30 to 40, or approximately 30 to 100 pounds overweight, who have failed to lose weight through diet and exercise. The system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed. We believe the Obalon Balloon System provides a cost-effective, non-surgical and reversible treatment for weight loss solution in an outpatient setting.

The Obalon Balloon System consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Obalon Navigation System console, which is a combination of hardware and software used to track and display the location of the balloon during placement without x-ray; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas. Placement of a balloon typically occurs in less than 15 minutes and can be accomplished in an outpatient setting without the need for anesthesia or sedation. Patients receive a total of three balloons over the course of eight to 12 weeks and all balloons are removed six months after the first balloon is placed.

In clinical studies, the Obalon Balloon System has demonstrated clinically meaningful weight loss with durable results. In our published pivotal SMART trial, patients in the Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham-control group, with an average of 15.1 pounds of weight loss, resulting in an average 6.9% reduction in total body weight and an average 2.4 point decrease in BMI. In the study, 66.7% of patients lost at least 5% of their total body weight and the study showed statistically significant improvements in cardiometabolic risk factors, including fasting glucose, systolic blood pressure, cholesterol and triglycerides. Patients in the treatment group were followed for 48 weeks and showed, on average, that 89.5% of the weight loss achieved during the initial 24-week balloon treatment period was maintained at 48 weeks, or 24 weeks after the balloons were removed.

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

We commenced U.S. commercialization of our prior generation Obalon balloon system in January 2017. In March 2020, we announced that the overall economic uncertainty, the restriction on elective procedures and the specific directives issued by the Governor of California as a result of the COVID-19 pandemic had a significant impact on our business. As a result, we halted sales to new patients in our Obalon-branded retail treatment centers, terminated expansion plans for additional retail centers, subsequently closed the two retail treatment centers we had opened and halted manufacturing. Additionally, since August 2020, we have only had two full-time employees: Andy Rasdal, our President and Chief Executive Officer, and Nooshin Hussainy, our Chief Financial Officer. Although we scaled back operations, we continued to strive to execute on our corporate and strategic objectives. For example, we continue to pursue third-party reimbursement of the Obalon Balloon System, explore strategic alternatives, tend to our obligations to care for patients who had been treated at our Obalon-branded retail treatment centers, follow-up on and support product-related issues involving customers that have used Obalon products, and review and comply with our regulatory obligations, including FDA and SEC requirements.

Given those impacts and the significant concern about an economic recovery that would allow consumers to feel confident enough to spend on a cash-pay procedure like the Obalon Balloon System, we do not currently plan to re-open our retail treatment centers, re-initiate our retail treatment center expansion plans, or plan to ship orders to U.S. customers or our former international distributor. As a result, we would not expect to report any new revenue for the foreseeable future.

We generated total revenue of $1.6 million and $3.3 million for the years ended December 31, 2020 and 2019, respectively. For the years ended December 31, 2020 and 2019, our net loss was $12.3 million and $23.7 million, respectively. We have not been profitable since inception, and as of December 31, 2020, our accumulated deficit was $184.8 million. From inception through December 31, 2020, we have financed our operations primarily through private placements of our preferred stock, the sale of common stock in our IPO and in subsequent public and private placements, and, to a lesser extent, debt financing arrangements.

On April 22, 2020, we executed a promissory note in favor of Silicon Valley Bank evidencing an unsecured loan in the aggregate principal amount of $0.4 million, which was made pursuant to the Paycheck Protection Program and which we refer to as the PPP Loan. The Paycheck Protection Program was established under the Coronavirus Aid, Relief and Economic Security Act, which was enacted on March 27, 2020 and is administered by the U.S. Small Business Administration. All the funds under the PPP Loan were disbursed to us on April 23, 2020. As of December 31, 2020, we had cash and cash equivalents of $3.9 million.

In the fourth quarter of 2020, we determined that the timeline for obtaining third-party reimbursement was longer than the cash runway available and we ceased our efforts related to reimbursement, including terminating its agreement with Blue Ox. We then focused its full efforts on consummating a strategic alternative transaction that would be in the best interest of our stockholders. On November 10, 2020, we signed a non-binding term sheet for merger with ReShape Lifesciences Inc. and, on January 20, 2021, announced that a definitive agreement had been signed on January 19, 2021 for a merger with ReShape Lifesciences Inc.

Landlord Dispute

On October 13, 2020, Gildred served the Company with an unlawful detainer action in the Superior Court of California, County of San Diego (Gildred Development Company v. Obalon Therapeutics, Inc., Case No. 37-2020-00035927-CU-UD-CTL). Gildred alleges that the Company owes more than $113,000 of unpaid rent and fees to Gildred and seeks damages for unpaid rent and continued occupancy of the premises. The Company believes Gildred's claims are without merit and will defend vigorously against them. On November 18, 2020, Gildred filed an ex parte application for a writ of attachment or, in the alternative, a temporary protective order. The application was denied on November 24, 2020. On December 28, 2020, Gildred filed another application for a writ of attachment or, in the alternative, a temporary protective order. On January 22, 2021, the court granted Gildred's application for a writ of attachment. Obalon has paid the amount of the writ in full, which was $338,000, and the parties are working toward a resolution of the action. The Company is current with its rent obligations under the lease with Gildred.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Revenue

For the year ended December 31, 2020 and 2019, revenue reflects sales of our Obalon Balloon System directly to physicians and institutions in the United States, sales of our Obalon Balloon System to our former Middle East distributors, and sales from patients treated at our Company-managed Obalon-branded retail center. We also generated revenue during the year ended December 31, 2020 from reversing various reserves related to revenue from customer incentive programs, our swallow guarantee, and returns reserves as a result of terminating all our commercial operations and underlying programs.

We do not currently plan to re-open our retail treatment centers, re-initiate our retail treatment center expansion plans, restart manufacturing operations, or plan to ship orders to U.S. customers or our former international distributor. As a result, we would not expect to report any meaningful revenue for the foreseeable future.

To date we have experienced limited penetration of the U.S. market, and there are many factors that may impact our future results of operations, including: our ability to complete with the Merger with ReShape, establish insurance coverage and reimbursement for the Obalon Balloon System, our ability to successfully develop the intragastric balloon market (which is currently small and immature) and gain acceptance of our current Obalon Balloon System and its future iterations by doctors and patients, our ability to scale production in a cost effective manner or if at all should we restart manufacturing operations, the emergence of competing products, actions by regulatory bodies, and general economic trends. The amount of revenue and timing of revenue recognition may also be impacted by any future commercial model and customer incentive programs we decide to offer and the channels through which the revenue is derived.

Cost of revenue and gross margin

Cost of revenue consists primarily of costs related to the direct materials and direct labor that are used to manufacture our products and the overhead costs that directly support manufacturing. Currently, a significant portion of our cost of revenue consists of manufacturing overhead, which is mostly fixed in nature. These overhead costs include the costs of compensation for operations management, engineering support, material procurement and inventory control personnel, outside consultants, production related supplies, allocated quality assurance and facilities costs, and depreciation on production equipment. In the foreseeable future, our costs of revenue may be greater than our revenue as we focus on the Merger with ReShape and in the alternative, reimbursement activities rather than commercial sales.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, geographic mix, product mix, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect gross margin to fluctuate from quarter to quarter due to variability of our recognized revenue, our adoption of new manufacturing processes and technologies, changes in our manufacturing capacity, and discontinuation of obsolete products. We have experienced challenges in our ability to produce finished goods, which may impact our ability to meet the demands for future commercial and clinical trials.

In March 2020, we suspended manufacturing of the Obalon Balloon System due to the ongoing COVID-19 pandemic. We restarted manufacturing on a limited basis in June 2020 to convert a small amount of work-in-progress inventory to finished goods, in order to have units available for clinical trials and unexpected physician sales, but did not continue manufacturing past July 30, 2020. As of December 31, 2020, our manufacturing operations have been suspended with no future plans for restarting.

Research and development expenses

Research and development, or R&D, expenses consist of the cost of engineering, clinical affairs, regulatory affairs and quality assurance associated with developing our Obalon Balloon System. R&D expenses consist primarily of:

- employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;

- cost of outside consultants who assist with technology development, regulatory affairs, clinical affairs and quality assurance;
- cost of clinical trial activities performed by third-party medical partners; and
- cost of facilities, depreciation on R&D equipment and supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. We expect R&D expenses as a percentage of total revenue to vary over time depending on the level of revenue, the timing of our new product development efforts, as well as our clinical development, clinical trial, FDA required post approval studies and other related activities.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, commissions, benefits, travel expense and stock-based compensation expense. Other SG&A expenses include promotional and advertising activities, marketing, conferences and trade shows, professional services fees, including legal fees, accounting fees, insurance costs, general corporate expenses, and allocated facilities-related expenses. SG&A expenses decreased significantly starting in the second quarter of 2020 due to suspension of business operations and the reduction of employee personnel to only certain key employees. SG&A expenses are expected to remain significantly lower than historical averages until such time when business operations may resume.

Impairment Expense

In light of recent events associated with the global spread of COVID-19 and other factors, we recognized an impairment expense for impairment of inventory and long-lived assets pertaining our retail operations during the second quarter of 2020.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue recognition

We recognize revenue, in accordance with ASC 606, when control of our products is transferred to our customers in an amount that reflects the consideration we expect to receive in exchange for those products. Our revenue recognition process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the transaction price, allocating the transaction price to the distinct performance obligations in the contract, and recognizing revenue as performance obligations are satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. We consider a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the

customer has the ability to use and obtain the benefit of the good or service. We recognize revenue for satisfied performance obligations only when we determine there are no uncertainties regarding payment terms or transfer of control.

Revenue is primarily generated from sales of the Obalon Balloon System to physicians and institutions in the United States, patients treated at the Obalon branded retail center, and sales to distributors in the Middle East. In sales to these customers, we recognize revenue upon shipment of its product as our standard contract terms dictate that control transfers to the customer upon shipment of its product. Invoicing typically occurs upon shipment and the time period between invoicing and when payment is due is not significant. Sales taxes collected are excluded from revenues. Shipping charges billed to customers are included in revenue and related shipping cost is included in cost of revenue. Our revenue contracts do not provide for maintenance. Revenue generated from the treatment centers that began treating patients in October 2019 is recognized as the distinct service performance obligations are delivered to customers. Commissions are considered incremental costs to obtain a contract with a customer and paid to salespeople when contracts are executed. Commissions from both private practice and treatment center revenues are recognized as a selling expense when incurred as the amortization period is one year or less.

The components of the Obalon Balloon System, in sales to physicians and Middle East distributors, are typically packaged in a kit and shipped to the customer at the same time, satisfying the majority of performance obligations in the contract. Revenues from the treatment center are recognized as we deliver the distinct performance obligations. We record deferred revenue at the treatment center whenever we receive cash payments prior to the fulfillment of the distinct performance obligations. We recognize revenue for any unsatisfied, distinct performance obligations, such as undelivered components, as they are satisfied based on the estimated standalone selling price of each performance obligation. We estimate the standalone selling price of each performance obligation by estimating the expected cost of satisfying that performance obligation plus an appropriate margin and also third-party evidence from certain performance obligations from treatment center revenues.

When we enter into contracts with multiple performance obligations, such obligations are generally satisfied within a short time frame of approximately three to six months after the contract execution date. We do not disclose the value of the unsatisfied performance obligations within our contracts.

We offer a swallow guarantee program in the United States where it may provide replacement balloons to customers when their patients are unsuccessful in swallowing an Obalon balloon, subject to certain requirements and restrictions. We consider the replacement balloons provided under this program as an additional performance obligation in the contract and we defer revenue related to the replacement balloons based on an expected swallow failure rate and then recognizes revenue when replacement balloons are provided.

We recognize revenue at the net sales price, which reflects the consideration we believe we are most likely to receive. The net sales price includes estimates of variable consideration for customer incentives and returns. We reserve for product returns as a reduction to revenue in the period when the related revenue is recognized. We estimate our product returns based on historical return rates and specifically known events. Estimated costs of customer incentive programs are recorded at the time the incentives are offered, based on the specific terms and conditions of the program. Customer incentives that provide discounts to the customer on purchases of current or future product are recorded as a reduction of revenue in the period the related product revenue is recognized. Any consideration payable to a customer is presumed as a reduction to revenue unless we can demonstrate that the consideration provided to the customer is in exchange for a distinct good or service.

Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary from our estimates, we would adjust these estimates, which would impact net product revenue and results of operations in the period such variances become known.

Research and Development Costs

All research and development costs are charged to expense as incurred. Research and development expenses primarily include (i) payroll and related costs associated with research and development performed, (ii) costs related to clinical and preclinical testing of our technologies under development and (iii) other research and development expenses.

Leases

Effective January 1, 2019, we adopted ASC No. 2016-02, *Leases (Topic 842) ("ASU 2016-02" or "ASC 842")*, which supersedes the current accounting for leases, using the modified retrospective transition method. We have elected to apply the practical expedients allowed by the standard for existing leases. The new standard, while retaining two distinct types of leases, finance and operating, (i) requires lessees to record a right-of-use ("ROU") asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and recognize lease expense in a manner similar to current accounting, (ii) eliminates current real estate specific lease provisions, (iii) modifies the lease classification criteria and (iv) aligns many of the underlying lessor model principles with those in the new revenue standard. We determine the initial classification and measurement of its ROU asset and lease liabilities at the lease commencement date and thereafter, if modified. We recognize a ROU asset for its operating leases with lease terms greater than 12 months. The lease term includes any renewal options and termination options that we are reasonably assured to exercise. The present value of lease payments is determined by using the incremental borrowing rate for operating leases determined by using the incremental borrowing rate of interest that we would pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment and term. We applied the new guidance to our existing facility lease at the time of adoption and recognized a ROU asset and lease liability of $0.0 million and $0.0 million, respectively, during the first quarter of 2020.

Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in research and development and general and administrative expenses in the statements of operations.

Variable Interest Entities

We evaluate our ownership, contractual and other interests in entities that are not wholly-owned to determine if these entities are VIEs, and, if so, whether we are the primary beneficiary of the VIE. In determining whether we are the primary beneficiary of a VIE and therefore required to consolidate the VIE, we apply a qualitative approach that determines whether we have both (1) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and (2) the obligation to absorb losses of, or the rights to receive benefits from, the VIE that could potentially be significant to that VIE. We continuously assesses whether we are the primary beneficiary of a VIE, as changes to existing relationships or future transactions may result in the consolidation or deconsolidation of such VIE.

RESULTS OF OPERATIONS

	Year ended December 31,	
	2020	2019
Consolidated statements of operations data:		
Revenue	$ 1,588	$ 3,281
Cost of revenue	1,004	2,950
Gross profit	584	331
Operating expenses:		
Research and development	2,450	6,893
Selling, general and administrative	8,776	16,668
Asset impairment and other charges	1,310	—
Total operating expenses	12,536	23,561
Loss from operations	(11,952)	(23,230)
Interest income (expense), net	29	(385)
Other expense, net	(411)	(61)
Net loss	(12,334)	(23,676)
Other comprehensive income (loss)	—	—
Net loss and comprehensive loss	$ (12,334)	$ (23,676)

Comparison of years ended December 31, 2020 and 2019

Revenue. Revenue decreased $1.7 million to $1.6 million during the year ended December 31, 2020, compared to $3.3 million during the year ended December 31, 2019. During the second quarter of 2020, we fundamentally changed our commercialization efforts and restructured operations, eliminating the field sales force and transitioned to a centralized customer support model to support our existing physician customers. We launched the first Obalon branded retail center during September 2019, as part of our strategy of shifting towards a retail treatment center business model, which we subsequently closed in the second quarter of 2020. As a result, revenue from U.S sales decreased $1.1 million stemming from selling fewer balloons in the U.S. Furthermore, sales to our Middle East distributors in 2020 declined $0.6 million over 2019 sales outside the U.S.

Cost of revenue and gross profit. Cost of revenue decreased $1.9 million to $1.0 million during the year ended December 31, 2020, compared to $3.0 million during the year ended December 31, 2019. The decrease was primarily attributable to a decrease in production of products as we suspended operations and abandoned the retail treatment model in the second quarter of 2020. Gross margin decreased to 36.8% during the year ended December 31, 2020, compared to 10.1% during the year ended December 31, 2019.

Research and development expenses. R&D expenses decreased $4.4 million to $2.5 million during the year ended December 31, 2020, compared to $6.9 million during the year ended December 31, 2019. This decrease was due primarily driven by a decrease of $3.9 million in payroll and R&D related project expenses and $0.5 million in stock-based compensation due to the significant reduction in operations and personnel related to the COVID-19 pandemic.

Selling, general and administrative expenses. SG&A expenses decreased $7.9 million to $8.8 million during the year ended December 31, 2020, compared to $16.7 million during the year ended December 31, 2019. The decrease from the prior period was primarily driven by the significant reduction in operations and personnel related to the COVID-19 pandemic. The reduction in operations and personnel resulted in decreases of $3.2 million in spending on marketing due to the closures of the retail centers, $2.7 million in payroll and office related expenses, $1.5 million in stock-based compensation due to a reduction in headcount and $0.5 million in accounting and legal fees.

Asset impairment expenses and other charges. Asset impairment expenses and other charges increased $1.3 million during the year ended December 31, 2020, compared to zero during the year ended December 31, 2019. The increase is due to the inventory and long-lived asset impairment charges recognized during the second quarter of 2020 as a result of our shift in business strategy away from the Obalon-branded retail center model to a reimbursement model strategy.

Interest expense, net. Interest expense, net decreased $0.4 million to $0.0 million during the year ended December 31, 2020, compared to $0.4 million during the year ended December 31, 2019. This decrease was attributable to paying off the Term Loan during the third quarter of 2019.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2020, we had cash and cash equivalents of $3.9 million and an accumulated deficit of $184.8 million. Our primary sources of capital have been private placements of our preferred securities, the sale of common stock in our initial Public Offering or IPO, in October 2016, a subsequent private placement in August 2018, and various equity financings in 2019 including a follow-on offering in August 2019, and, to a lesser extent, debt financing arrangements. We are continuing to significantly reduce expenditures to extend our cash runway during the suspension of our business operations. From January 1, 2021 through March 2, 2021, the Company's warrant holders covering 2.3 million shares exercised the warrants and common stock was issued in exchange for proceeds of $9.5 million. We believe our current cash and cash equivalents as of December 31, 2020 and cash received from exercise of warrants in the first quarter of 2021 are sufficient to fund our operations through the end of March 2022.

In late 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread globally. To date, COVID-19 has had, and will continue to have, an adverse impact on our operations and expenses as a result of the preventive and precautionary measures that we, our customers, other businesses, and governments are taking, including the deferral of elective medical procedures and diversion of capital and other resources. In March 2020, we suspended all new patient treatments at our Obalon-branded retail centers due to the ongoing COVID-19 pandemic. We have taken further steps to significantly reduce expenses in an effort to extend our cash runway while we evaluate potential business options, strategic alternatives and the potential for third-party payer reimbursement that may be available when and if the current COVID-19 crisis stabilizes and the economy rebounds. We have significantly reduced the organization to only essential personnel and since August 2020, only two full-time employees remain. All Obalon-branded retail centers have been shut down with no intention to reopen, and we have halted plans for future retail center expansion. We do not expect to restart shipments to U.S. customers and we have terminated the agreement with our international distributor, Al Danah Medical Company W.L.L. The decision to shift our strategy to focus on pursuing reimbursement, while also evaluating other strategic options, occurred after the end of the first quarter of 2020. Since reducing our personnel to two full time employees, we have continued to seek strategic alternatives that may be in the best interest of our stockholders, while we pursue third-party payor reimbursement and coverage for the Obalon Balloon System. If we are unsuccessful in those two endeavors over the next several months, there is a high likelihood we may need to liquidate all or some of our assets or seek bankruptcy protection which could result in significant decrease in value for all stakeholders.

Although we have scaled back operations, we continue our operations and strive to execute on our corporate and strategic objectives. For example, we tend to our obligations to care for patients treated at the Obalon Centers for Weight Loss, follow-up on and support product-related issues involving customers that have used Obalon products, review and comply with our regulatory obligations, including FDA and SEC requirements, and will continued to pursue third-party reimbursement of the Obalon Balloon System. We have also sought strategic alternatives and on January 19, 2020 entered into the Merger Agreement with ReShape and have suspended reimbursement activities to focus primarily on consummating the Merger.

On April 22, 2020, we executed a promissory note in favor of Silicon Valley Bank evidencing an unsecured loan in the aggregate principal amount of $0.4 million, which was made pursuant to the Paycheck Protection Program and which we refer to as the PPP Loan. The Paycheck Protection Program was established under the Coronavirus Aid, Relief and Economic Security Act, which was enacted on March 27, 2020, and is administered by the U.S. Small Business Administration. All the funds under the PPP Loan were disbursed to us on April 23, 2020. The Note provides for a fixed interest rate of one percent per year with a maturity date of April 22, 2022 (the "Maturity Date"). Loan payments may be deferred until August 2021, which date is 10 months after the end of our 24-week covered period for the PPP Loan. If we apply for loan forgiveness, loan payments may be deferred until the SBA remits our loan forgiveness amount to the lender. As of December 31, 2020, we have not applied for loan forgiveness. The PPP Loan may be prepaid at any time prior to the Maturity Date with no prepayment penalties or premiums. The Note contains customary event of default provisions.

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loans granted under the PPP. Such forgiveness will be subject to approval by the SBA and the Lender and determined, subject to limitations, based on factors set forth in the CARES Act, including verification of the use of loan proceeds for payment of payroll costs and payments of mortgage interest, rent and utilities. In the event the PPP Loan, or any portion thereof, is forgiven, the amount forgiven is applied to outstanding principal. The terms of any forgiveness may also be subject to further regulations and guidelines that the SBA may adopt. We will carefully monitor all qualifying expenses and other requirements necessary to attain loan forgiveness; however, no assurance is provided that we will obtain forgiveness of the PPP Loan in whole or in part. We have used all proceeds to date from the PPP Loan to retain employees, maintain payroll and make lease and utility payments. We have not filed for forgiveness and the loan will be repayable in full in the event of a change of control, such as the proposed Merger, unless the lender agrees to transfer the loan.

Public Offering

On August 1, 2019, we entered into an underwriting agreement with A.G.P./Alliance Global Partners, as underwriter, in connection with a public offering of our securities, pursuant to which we issued and sold (i) 2,427,500 shares of our common stock (including 412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of our common stock , (iii) accompanying warrants to purchase up to 3,234,375 shares of our common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) and (iv) an additional warrant to the underwriters for the purchase of 37,500 shares of our common stock resulting in net proceeds from the offering of approximately $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by us. Each share of common stock and each prefunded warrant was sold together with a purchase warrant entitling the holder to purchase 0.75 of a share of common stock. The common stock and accompanying purchase warrants were sold together at a public offering price of $4.00, and the pre-funded warrant and accompanying purchase warrants were sold at a public offering price of $3.999. The purchase warrants were immediately exercisable upon issuance, will expire on August 6, 2024 and have an exercise price of $4.40 and the underwriter warrant has an exercise price of $5.00 per share, in each case subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events. The underwriter warrant became exercisable in February 2020 and expires on August 6, 2024. All of the pre-funded warrants were exercised during the third quarter of 2019. None of the purchase or underwriter warrants have been exercised as of December 31, 2020. As of December 31, 2020, none of the purchase or underwriter warrants have been were exercised, however, since December 31, 2020, we received proceeds of approximately $9.5 million as a result of the exercise of 2.3 million purchase warrants as of December 31, 2020.

Lincoln Park Purchase Agreement

On February 5, 2020, we entered into a new purchase agreement (the "Purchase Agreement") and registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $15.0 million of our common stock, $0.001 par value per share (the "Common Stock"). The new Purchase Agreement replaces an existing purchase agreement, dated December 27, 2018, by and between us and Lincoln Park, pursuant to which Lincoln Park committed to purchase up to $20.0 million of our Common Stock. In connection with entering into the new Purchase Agreement, we terminated the prior purchase agreement with Lincoln Park, effective February 5, 2020.

Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of our Common Stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on February 28, 2020 date that a registration statement covering the resale of shares of Common Stock that have been and may be issued under the Purchase Agreement, which we agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement, was declared effective by the SEC and a final prospectus in connection therewith was filed and the other conditions set forth in the purchase agreement were satisfied (such date on which all of such conditions are satisfied, the "Commencement Date").

We incurred approximately $0.3 million of legal, accounting, and other fees related to the offering. As of December 31, 2020 we have not sold any shares under the Purchase Agreement to Lincoln Park. As a result, we fully expensed the $0.3 million of fees in March 2020.

CASH FLOWS

The following table provides a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Year ended December 31,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (10,409)	(22,866)
Investing activities	(171)	2,356
Financing activities	430	13,378
Net (decrease) increase in cash and cash equivalents	$ (10,150)	$ (7,132)

Net cash used in operating activities

During the year ended December 31, 2020, net cash used in operating activities was $10.4 million, consisting primarily of a net loss of $12.3 million, an increase in net operating assets of $1.4 million primarily related to a decrease in accrued compensation as a result of the reduction in full-time employees to two as of December 31, 2020. These items were further offset by non-cash charges of $3.3 million, consisting primarily of stock-based compensation expense, depreciation expense, impairment of long-lived assets and amortization expense of right-of-use assets.

During the year ended December 31, 2019, net cash used in operating activities was $22.9 million, consisting primarily of a net loss of $23.7 million, partially offset by a decrease in net operating assets of $3.3 million primarily related to a decrease in accrued compensation as a result of the April 2019 internal restructuring. These items were further offset by non-cash charges of $4.1 million, consisting primarily of stock-based compensation expense, depreciation expense, and amortization expense of right-of-use assets.

Net cash (used in) provided by investing activities

During the year ended December 31, 2020, net cash used in investing activities was $0.2 million, consisting of monies used to purchase equipment.

During the year ended December 31, 2019, net cash provided by investing activities was $2.4 million, consisting primarily of maturities of short-term investments, partially offset by purchases of short-term investments and capital expenditures.

Net cash provided by financing activities

During the year ended December 31, 2020, net cash provided by financing activities was $0.4 million, consisting of proceeds from the Payment Protection Program loan.

During the year ended December 31, 2019, net cash provided by financing activities was $13.4 million, consisting primarily of proceeds from issuance of common stock (net of issuance costs) of $17.0 million, proceeds from the exercise of prefunded warrants of $6.4 million, and proceeds from the long-term loan of $10.0 million, offset by payments of the long-term loan of $20.0 million.

OFF-BALANCE SHEET ARRANGEMENTS

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities or variable interest entities.

EFFECTS OF INFLATION

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

RECENT ACCOUNTING PRONOUNCEMENTS

See “Notes to the Consolidated Financial Statements-Note 2-Recent Accounting Pronouncements” of our annual financial statements.

JOBS ACT ACCOUNTING ELECTION

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

ITEM 8. Financial Statements and Supplementary Data

The financial statements and supplemental data required by this item are set forth at the pages indicated in Part IV, Item 15(a)(1) of this Annual Report on Form 10-K.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is designed 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 in the United States of America. Our internal control over financial reporting includes those policies and procedures that:

(i) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. Management reviewed the results of its assessment with the audit committee of our board of directors.

Based on that assessment under the framework in Internal Control-Integrated Framework (2013), management concluded that the company's internal control over financial reporting was effective as of December 31, 2020.

This annual report on Form 10-K does not include an attestation report of our company's registered public accounting firm regarding internal control over financial reporting as we are an Emerging Growth Company as of December 31, 2020, as defined in JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. Executive Compensation

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

Financial Statements and Financial Statement Schedules

We have filed the following financial statements and financial statement schedules as part of this Annual Report:

Exhibits

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Obalon Therapeutics, Inc.
Carlsbad, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Obalon Therapeutics, Inc. (the "Company") as of December 31, 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2020, 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 at December 31, 2020, and the results of its operations and its cash flows for the year 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 the Company's consolidated financial statements based on our audit. 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 audit 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 consolidated 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2021.

Costa Mesa, California
March 12, 2021

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Obalon Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Obalon Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2019, and the related notes (collectively, 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, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audit. We are a public accounting firm registered with the 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 audit 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

We served as the Company's auditor since 2015 to 2021.

San Diego, California
February 27, 2020

OBALON THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and par value data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 3,905	$ 14,055
Accounts receivable, net	—	285
Inventory	—	1,936
Other current assets	3,930	1,959
Total current assets	7,835	18,235
Lease right-of-use assets	521	1,077
Property and equipment, net	957	1,081
Clinical-use assets	1,304	—
Total assets	$ 10,617	$ 20,393
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 615	$ 648
Accrued compensation	65	820
Deferred revenue	—	424
Other current liabilities	3,802	1,524
Current portion of lease liabilities	564	561
Total current liabilities	5,046	3,977
Lease liabilities, long-term	438	567
Long-term debt	430	—
Other long-term liabilities	38	—
Total liabilities	5,952	4,544
Commitments and contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 7,770,698 and 7,724,100 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	8	8
Additional paid-in capital	189,421	188,271
Accumulated deficit	(184,764)	(172,430)
Total stockholders' equity	4,665	15,849
Total liabilities and stockholders' equity	$ 10,617	$ 20,393

See accompanying notes to consolidated financial statements.

OBALON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except shares and per share data)

	Year ended December 31,	
	2020	2019
Revenue:		
Revenue	$ 1,588	$ 3,281
Total revenue	1,588	3,281
Cost of revenue	1,004	2,950
Gross profit	584	331
Operating expenses:		
Research and development	2,450	6,893
Selling, general and administrative	8,776	16,668
Asset impairment and other charges	1,310	—
Total operating expenses	12,536	23,561
Loss from operations	(11,952)	(23,230)
Interest income (expense), net	29	(385)
Other expense	(411)	(61)
Net loss	(12,334)	(23,676)
Other comprehensive income	—	—
Net loss and comprehensive loss	$ (12,334)	$ (23,676)
Net loss per share, basic and diluted	$ (1.59)	$ (5.03)
Weighted-average common shares outstanding, basic and diluted	7,738,355	4,706,775

See accompanying notes to consolidated financial statements.

OBALON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except shares and per share data)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2018	2,351,333	$ 2	$ 161,859	$ (148,754)	$ 13,107
Stock-based compensation	—	—	2,983	—	2,983
Issuance of common stock for cash upon exercise of stock options	119	—	—	—	—
Vesting of early exercised stock options	—	—	58	—	58
Issuance of common stock and warrants, net of issuance costs	3,661,238	4	23,362	—	23,366
Exercise of warrants for the purchase of common stock	1,735,000	2	—	—	2
Cancellation of restricted stock awards	(26,910)	—	—	—	—
Issuance of round up common stock for reverse stock split	3,320	—	9	—	9
Net loss	—	—	—	(23,676)	(23,676)
Balance at December 31, 2019	7,724,100	8	188,271	(172,430)	15,849
Stock-based compensation	—	—	1,089	—	1,089
Vesting of stock awards, net of cancellations	7,533	—	—	—	—
Vesting of early exercised stock options	—	—	16	—	16
Issuance of warrants for the purchase of common stock	—	—	45	—	45
Vesting of restricted stock, net of cancellations	39,065	—	—	—	—
Net loss	—	—	—	(12,334)	(12,334)
Balance at December 31, 2020	7,770,698	$ 8	$ 189,421	$ (184,764)	$ 4,665

See accompanying notes to consolidated financial statements.

OBALON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,	
	2020	2019
Operating activities:		
Net loss	$ (12,334)	$ (23,676)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	340	479
Stock-based compensation	1,089	2,983
Fair value of cash-settled options	38	—
Issuance of warrants	45	—
Amortization of right-of-use assets	503	415
Loss on disposal of fixed asset	—	128
Accretion of investment discount, net	—	(2)
Amortization of debt discount	—	70
Impairment of long-lived assets and other charges	1,257	—
Impairment of inventory	53	—
Change in operating assets and liabilities:		
Accounts receivable, net	285	585
Inventory	(525)	12
Other current assets	(1,804)	411
Accounts payable	(33)	(543)
Accrued compensation	(740)	(2,985)
Deferred revenue	(424)	72
Lease liabilities, net	(427)	(364)
Other current and long-term liabilities	2,268	(451)
Net cash used in operating activities	(10,409)	(22,866)
Investing activities:		
Maturities of short-term investments	—	2,550
Purchases of property and equipment	(171)	(194)
Net cash (used in) provided by investing activities	(171)	2,356
Financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	—	23,377
Proceeds from long-term loan, net of issuance costs	430	10,000
Repayments of long-term loans	—	(20,000)
Proceeds from sale of common stock upon exercise of stock options	—	1
Net cash provided by financing activities	430	13,378
Net (decrease) increase in cash and cash equivalents	(10,150)	(7,132)
Cash and cash equivalents at beginning of period	14,055	21,187
Cash and cash equivalents at end of period	$ 3,905	$ 14,055
Supplemental cash flow information:		
Interest paid	$ —	$ 719
Income taxes paid	$ —	$ —
Property and equipment in accounts payable	$ —	$ 32

See accompanying notes to consolidated financial statements.

OBALON THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

Obalon Therapeutics, Inc., or the Company, was incorporated in the state of Delaware on January 2, 2008. The Company is a vertically-integrated medical device company focused on developing and commercializing innovative medical devices to treat obesity. Using its patented technology, the Company has developed the Obalon® balloon system, the first and only U.S. Food and Drug Administration, or FDA, approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients.

Basis of Presentation

The consolidated financial statements include the accounts of Obalon Therapeutics, Inc., and its wholly owned subsidiary, Obalon Center for Weight Loss, Inc.

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, and include the Company's accounts and accounts of its wholly-owned subsidiary. The Company also consolidates variable interest entities ("VIE") for which it is the primary beneficiary. The primary beneficiary has both (a) the power to direct the activities of the VIE that most significantly affect the entity's economic performance and (b) either the obligation to absorb losses or the right to receive benefits. Refer to Note 11, "Variable Interest Entity" for further details. All intercompany transactions and balances have been eliminated in consolidation.

The Company's principal operations are located in Carlsbad, California and it operates in one business segment.

Reverse Stock Split

On July 24, 2019, the Company filed a certificate of amendment to its certificate of incorporation with the Secretary of State of the State of Delaware to effect a one-for-ten reverse split of its issued and outstanding common stock. The accompanying consolidated financial statements and notes thereto give retrospective effect to the reverse stock split for all periods presented. All issued and outstanding common stock, options exercisable for common stock, restricted stock units, performance restricted stock units, and per share amounts contained in the consolidated financial statements have been retrospectively adjusted to reflect this reverse stock split for all periods presented. The number of authorized shares of common stock will not be changed by virtue of the reverse stock split and will remain at 100.0 million shares.

Liquidity

As of December 31, 2020, the Company has devoted a substantial portion of its efforts to product development, raising capital, and building infrastructure, and, since January 2017, U.S. commercialization. The Company has incurred operating losses and has experienced negative cash flows from operations since its inception. In July 2012, the Company realized initial revenue from its planned principal operations. The Company recognized total revenue of $1.6 million and $3.3 million for the years ended December 31, 2020 and 2019, respectively. However, the Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and has funded its activities to date almost exclusively from debt and equity financings.

As reflected in the accompanying consolidated financial statements, the Company has a limited operating history and the sales and income potential of the Company's business are unproven. The Company has not been profitable since inception, and as of December 31, 2020, its accumulated deficit was $184.8 million. Since inception, the Company has financed its operations primarily through private placements of its preferred stock, the sale of common stock in its IPO and in subsequent public and private placements, and, to a lesser extent, debt financing arrangements.

The Company may need additional funding to pay expenses relating to its operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding, if needed, may not be available to the Company on acceptable terms, or at all. The failure to consummate the Merger with ReShape or alternatively, obtain sufficient funds on acceptable terms could have a material adverse effect on the Company's business, results of operations or financial condition.

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. In late 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread globally. To date, COVID-19 has had, and will continue to have, an adverse impact on the Company's operations and expenses. In March 2020, the Company suspended all new patient treatments at our Obalon-branded retail centers due to the ongoing COVID-19 pandemic. The Company has taken further steps to significantly reduce expenses in an effort to extend our cash runway while the Company evaluates potential business options, strategic alternatives and the potential for third-party payer reimbursement that may be available when and if the current COVID-19 crisis stabilizes and the economy rebounds. The Company has significantly reduced the organization to only essential personnel and since August 2020, only two full-time employees remain. All Obalon-branded retail centers have been shut down with no intention to reopen, and the Company has halted plans for future retail center expansion. The Company does not expect to restart shipments to U.S. customers and the Company has terminated the agreement with our international distributor, Al Danah Medical Company W.L.L. The decision to shift the Company's strategy to focus on pursuing reimbursement, while also evaluating other strategic options, occurred after the end of the first quarter of 2020.

As of February 27, 2020, the issuance date of the Company's consolidated financial statements for the year ended December 31, 2019, the Company had concluded that there was substantial doubt about its ability to continue as a going concern. As of December 31, 2020, the Company had $3.9 million in cash, cash equivalents, and marketable debt securities. From January to March 2021, the Company's warrants holders exercised warrants for 2,260,875 shares of common stock. The Company received aggregate gross proceeds from exercise of warrants of approximately $9.5 million, which has alleviated the substantial doubt about the Company's ability to continue as a going concern. The Company expects that its existing cash and cash equivalents, including the gross proceeds it received from January through March 2021, will be sufficient to fund its forecasted operating expenses, capital expenditures and debt service payments for at least the next twelve months from the issuance of these annual consolidated financial statements. However, there can be no assurance that the Company will be able to continue to raise additional capital in the future.

On November 10, 2020, Obalon signed a non-binding term sheet for merger with ReShape Lifesciences, Inc. and, on January 20, 2021, announced that a definitive agreement had been signed on January 19, 2021, for a merger with ReShape Lifesciences.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period.

Reported amounts and note disclosures reflect the overall economic conditions that are most likely to occur and anticipated measures management intends to take. Actual results could differ materially from those estimates. All revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

Fair Value Measurements

The carrying values of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their fair values due to the short maturity of these instruments. The carrying value of the term loan approximates its fair value as the interest rate and other terms are that which are currently available to the Company.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels in accordance with authoritative accounting guidance:

- Level 1 inputs: Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

- Level 2 inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

- Level 3 inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

Accounts Receivable

Receivables are unsecured and are carried at net realizable value including an allowance for estimated uncollectible amounts. Trade credit is generally extended on a short-term basis; thus trade receivables do not bear interest, although a finance charge may be applied to such receivables that are more than 30 days past due. The allowance for doubtful accounts is based on the Company's assessment of the collectability of customer accounts. The Company regularly reviews the allowance by considering factors such as historical expense, credit quality, the age of the account receivable balances, and current economic conditions that may affect a customer's ability to pay. Amounts determined to be uncollectible are charged or written off against the reserve. The Company's allowance for doubtful accounts was $0 million and $0.5 million at December 31, 2020 and 2019, respectively.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents and trade accounts receivable, which are generally not collateralized. The Company limits its exposure to credit loss by placing its cash equivalents with high credit quality financial institutions and investing in high quality short-term debt instruments. The Company's customers consist of physicians and institutions in the United States and one international distributor. The Company establishes customer credit policies related to its accounts receivable

based on historical collection experiences within the various markets in which the Company operates, historical past-due amounts, and any specific information that the Company becomes aware of such as bankruptcy or liquidity issues of customers.

The following table summarizes certain financial data for the customers who accounted for 10.0% or more of sales and accounts receivable.

	Year ended December 31,	
Revenue	2020	2019
Customer A	— %	19.7 %
Customer B	0.2 %	17.9 %
Customer C	30.2 %	9.1 %

Accounts Receivable	December 31, 2020	December 31, 2019
Customer A	— %	20.8 %

The Company's largest customer for the year ended December 31, 2020 was its Middle East distributor in Kuwait, and for the year ended December 31, 2019 the largest customer was a U.S. physician.

Inventory

Inventory is stated at the lower of cost (which approximates actual cost on a first-in, first-out basis) or net realizable value, computed on a standard cost basis. Inventory that is obsolete or is in excess of forecasted usage is written down to its estimated net realizable value based on assumptions about future demand. Inventory write-downs are charged to cost of revenue and establish a new cost basis for the inventory.

The Company evaluated whether the shift in business strategy to pursue a reimbursement model was indicative of inventory impairment. The Company performed an impairment assessment on its inventory stock and recognized $0.1 million in impairment charges for the year ended December 31, 2020 related to excess inventory not expected to be used in clinical trials to pursue reimbursement. The Company determined that the remaining inventory balance has an alternative future use in clinical trials and reclassified it to other current assets and clinical-use assets on its consolidated balance sheet as of December 31, 2020. As a result, the Company does not have any inventory as of December 31, 2020.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets. Maintenance and repairs are charged to expense as incurred. Assets not yet placed in use are not depreciated.

The useful lives of the property and equipment are as follows:

Computer hardware	3 years
Computer software	3 years
Leasehold improvements	Shorter of lease term or useful life
Furniture and fixtures	5 years
Scientific equipment	5 years

Impairment of Long-Lived Assets

The Company evaluates property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount of the assets to the future undiscounted net cash flows, which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the difference between the carrying amount and the fair value of the impaired asset.

In light of the Company's shift in business strategy from the Obalon-branded retail treatment center model to a reimbursement model, the Company performed an impairment analysis on its long-lived assets and recognized $1.2 million in impairment charges for the year ended December 31, 2020 relating to the assets as the Company's previous retail treatment centers.

The Company did not recognize any material impairment losses for the year ended December 31, 2019.

Leases

Effective January 1, 2019, the Company adopted ASC No. 2016-02, *Leases (Topic 842) ("ASU 2016-02" or "ASC 842")*, which supersedes the current accounting for leases, using the modified retrospective transition method. The Company has elected to apply the practical expedients allowed by the standard for existing leases. The new standard, while retaining two distinct types of leases, finance and operating, (i) requires lessees to record a right-of-use ("ROU") asset and a related liability for the rights and obligations associated with a lease, regardless of lease classification, and recognize lease expense in a manner similar to current accounting, (ii) eliminates current real estate specific lease provisions, (iii) modifies the lease classification criteria and (iv) aligns many of the underlying lessor model principles with those in the new revenue standard. The Company determines the initial classification and measurement of its ROU asset and lease liabilities at the lease commencement date and thereafter, if modified. The Company recognizes a ROU asset for its operating leases with lease terms greater than 12 months. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the incremental borrowing rate for operating leases determined by using the incremental borrowing rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment and term. The Company applied the new guidance to its existing facility lease at the time of adoption and recognized a ROU asset and lease liability of $1.2 million and $1.3 million, respectively, during the first quarter of 2019.

The Company recorded an immaterial amount of lease liabilities, ROU assets, and interest expense associated with finance leases as of and for the year ended December 31, 2020. The underlying asset utilized through the finance lease was purchased by the Company during the fourth quarter of 2020 and no further financing leases remained as of December 31, 2020. The current and long-term portions of operating lease liabilities are presented within the current portion of lease liabilities and lease liabilities long-term line items on the consolidated balance sheet, respectively. Operating lease ROU assets are presented within the lease right-of-use assets line item on the consolidated balance sheet.

Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in research and development and general and administrative expenses in the statements of operations.

Variable Interest Entities

The Company evaluates its ownership, contractual and other interests in entities that are not wholly-owned to determine if these entities are VIEs, and, if so, whether the Company is the primary beneficiary of the VIE. In determining whether the Company is the primary beneficiary of a VIE and therefore required to consolidate the VIE, the Company applies a qualitative approach that determines whether the Company has both (1) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and (2) the obligation to absorb losses of, or the rights to receive benefits from, the VIE that could potentially be significant to that VIE. The Company continuously assesses whether it is the primary beneficiary of a VIE, as changes to existing relationships or future transactions may result in the consolidation or deconsolidation of such VIE.

Research and Development Costs

All research and development costs are charged to expense as incurred. Research and development expenses primarily include (i) payroll and related costs associated with research and development performed, (ii) costs related to clinical and preclinical testing of our technologies under development and (iii) other research and development expenses.

Clinical Trial Expenses

The Company enters into contracts with third party hospitals and doctors to perform clinical trial activities. The Company accrues expenses for clinical trial activities performed by third parties based on estimates of work performed by each third party as of the balance sheet date. The Company's clinical trial expense is primarily driven by patient visits to the third party hospitals and doctors. As such, the Company accrues expense for actual patient visits based on third-party reporting and the contractually agreed upon cost for each visit to calculate its clinical accrual.

Stock-Based Compensation

Stock-based awards issued to employees and directors, are recorded at fair value as of the grant date and recognized as expense on a ratable basis over the employee's or director's requisite service period (generally the vesting period). The fair value of incentive stock options is estimated using the Black-Scholes option pricing model. The fair value of restricted stock awards and restricted stock units is estimated using the Company's stock price on the grant date. Because non-cash stock compensation expense is based on awards ultimately expected to vest, it is reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

Income Taxes

Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

The Company accounts for interest and penalties related to income tax matters, if any, as a component of income tax expense or benefit.

Revenue recognition

The Company recognizes revenue, in accordance with ASC 606, when control of its products is transferred to its customers in an amount that reflects the consideration it expects to receive in exchange for those products. The Company's revenue recognition process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the transaction price, allocating the transaction price to the distinct performance obligations in the contract, and recognizing revenue as performance obligations are satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Revenue is primarily generated from sales of the Obalon Balloon System to physicians and institutions in the United States, patients treated at the Obalon branded retail center, and sales to distributors in the Middle East. In sales to these customers, the Company recognizes revenue upon shipment of its product as the Company's standard contract terms dictate that control transfers to the customer upon shipment of its product. Invoicing typically occurs upon shipment and the time period between invoicing and when payment is due is not significant. Sales taxes collected are excluded from revenues. Shipping charges billed to customers are included in revenue and related shipping cost is included in cost of

revenue. The Company's revenue contracts do not provide for maintenance. Revenue generated from the treatment centers that began treating patients in October 2019 is recognized as the distinct service performance obligations are delivered to customers. Commissions are considered incremental costs to obtain a contract with a customer and paid to salespeople when contracts are executed. Commissions from both private practice and treatment center revenues are recognized as a selling expense when incurred as the amortization period is one year or less.

The components of the Obalon Balloon System, in sales to physicians and Middle East distributors, are typically packaged in a kit and shipped to the customer at the same time, satisfying the majority of performance obligations in the contract. Revenues from the treatment center are recognized as the Company delivers the distinct performance obligations. The Company records deferred revenue at the treatment center whenever the Company receives cash payments prior to the fulfillment of the distinct performance obligations. The Company recognizes revenue for any unsatisfied, distinct performance obligations, such as undelivered components, as they are satisfied based on the estimated standalone selling price of each performance obligation. The Company estimates the standalone selling price of each performance obligation by estimating the expected cost of satisfying that performance obligation plus an appropriate margin and also third-party evidence for certain performance obligations from treatment center revenues.

When the Company enters into contracts with multiple performance obligations, such obligations are generally satisfied within a short time frame of approximately three to six months after the contract execution date. The Company does not disclose the value of the unsatisfied performance obligations within its contracts.

The Company offers a swallow guarantee program in the United States where it may provide replacement balloons to customers when their patients are unsuccessful in swallowing an Obalon balloon, subject to certain requirements and restrictions. The Company considers the replacement balloons provided under this program as an additional performance obligation in the contract and defers revenue relating to the replacement balloons based on an expected swallow failure rate and then recognizes revenue when replacement balloons are provided.

The Company recognizes revenue at the net sales price, which reflects the consideration the Company believes it is most likely to receive. The net sales price includes estimates of variable consideration for customer incentives and returns. The Company reserves for product returns as a reduction to revenue in the period when the related revenue is recognized. The Company estimates its product returns based on historical return rates and specifically known events. Estimated costs of customer incentive programs are recorded at the time the incentives are offered, based on the specific terms and conditions of the program. Customer incentives that provide discounts to the customer on purchases of current or future product are recorded as a reduction of revenue in the period the related product revenue is recognized. Any consideration payable to a customer is presumed as a reduction to revenue unless the Company can demonstrate that the consideration provided to the customer is in exchange for a distinct good or service.

Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company would adjust these estimates, which would impact net product revenue and results of operations in the period such variances become known.

Product Warranty

The Company warranties its products to be of good quality and free from defects in design, materials, or workmanship for approximately one year from the date of purchase. The Company accrues for the estimated future costs of repair or replacement upon shipment. The warranty accrual is recorded to cost of revenue and is based on historical and forecasted trends in the volume of product failures during the warranty period and the cost to repair or replace the equipment.

It is possible that the Company's underlying assumptions will not reflect the actual experience and in that case, future adjustments will be made to the recorded warranty obligation. The warranty expense as of December 31, 2020 and 2019 was immaterial.

Advertising Costs

Advertising costs are expensed as incurred and included in selling, general and administrative expense. Advertising costs for the years ended December 31, 2020 and 2019 were approximately $0.1 million and $0.8 million, respectively.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per common share, since the effects of potentially dilutive securities are anti-dilutive due to the net loss position of all periods presented.

Potentially dilutive common stock equivalents are comprised of warrants, unvested restricted stock awards (RSAs), and unexercised stock options outstanding under the Company's equity plan.

Recently Issued and Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted-average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The adoption of the new standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements not yet adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, Financial Instruments - Credit Losses, which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. In February 2020, the FASB issued ASU 2020-02, Financial Instruments-Credit Losses (Topic 326) and Leases (Topic 842) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases (Topic 842), which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2022. The Company believes the adoption will modify the way the Company analyzes financial instruments, but it does not anticipate a material impact on results of operations. The Company is in the process of determining the effects the adoption will have on its consolidated financial statements.

In December 2019, the FASB issued authoritative guidance intended to simplify the accounting for income taxes: ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. This guidance eliminates certain exceptions to the general approach to the income tax accounting model and adds new guidance to reduce the complexity in accounting for income taxes. This guidance is effective for annual periods after December 15, 2020, including interim periods within those annual periods. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements.

3. Fair Value Measurements

Instruments Recorded at Fair Value on a Recurring Basis

The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

Assets and liabilities measured at fair value on a recurring basis at December 31, 2020 and 2019 are as follows (in thousands):

		Fair value measurements at reporting date using		
	Balance as of December 31, 2020	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash	$ 823	$ 823	—	—
Cash Equivalents:				
Money Market Funds	3,082	3,082	$ —	$ —
Total assets	$ 3,905	$ 3,905	$ —	$ —

		Fair value measurements at reporting date using		
	Balance as of December 31, 2019	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash	$ 1,012	$ 1,012	—	—
Cash Equivalents:				
Money Market Funds	13,043	13,043	—	—
Total assets	$ 14,055	$ 14,055	$ —	$ —

The Company's investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as of December 31, 2020 and 2019.

The warrant liabilities are recorded at fair value using the Black-Scholes option pricing model based on the following assumptions as of December 31, 2020:

	December 31, 2020
Assumed risk-free interest rate	0.38% - 0.44 %
Assumed volatility	69.86% - 70.84 %
Expected life	6.10 years
Expected dividend yield	— %

The assumptions were determined as follows:

Assumed risk-free interest rate — Based on the average yield of U.S. Treasury bills as of the valuation date for the expected term of the awards.

Assumed volatility — Based on the historical volatility of a number of publicly traded companies comparable in size, business model, industry and business description.

Expected life — Based on the remaining contractual term of warrant or the equity award as of the valuation date.

Expected dividend yield — Based upon the Company's historic dividends and dividend expectations for the foreseeable future.

As of December 31, 2020, reasonable changes in the unobservable inputs would not be expected to have a significant impact on the consolidated financial statements. The Company's policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no significant transfers into or out of Level 1, 2, or 3 for the year ended December 31, 2020.

The following table provides reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) for the year ended December 30, 2020 (in thousands):

	Fair value measurements at reporting date using significant unobservable inputs (Level 3)
Balance as of December 31, 2019	$ —
Issuance of cash settled equity awards	5
Change in fair value of warrant and cash settled award liabilities	33
Balance as of December 31, 2020	$ 38

Instruments Not Recorded at Fair Value on a Recurring Basis

The estimated fair value of the Company's long-term loan is determined by Level 2 inputs and is based primarily on quoted market prices for the same or similar issues. The recorded value of the Company's long-term loan approximates the current fair value as the interest rate and other terms are more favorable than that which are currently available to the Company.

4. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share of common stock (in thousands, except shares and per share data):

	Year ended December 31,	
	2020	2019
Net loss	$ (12,334)	$ (23,676)
Weighted-average common shares outstanding, basic and diluted	7,738,355	4,706,775
Net loss per share, basic and diluted	$ (1.59)	$ (5.03)

The following table sets forth the outstanding potentially dilutive securities determined using the treasury stock method that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive (in common stock equivalent shares):

	Year ended December 31,	
	2020	2019
Stock options to purchase common stock	1,099,855	518,468
Warrants to purchase common stock	3,371,875	3,271,875
Total	4,471,730	3,790,343

5. Balance Sheet Details

Inventory consists of the following (in thousands):

	December 31,	
	2020	2019
Raw materials	$ —	$ 1,835
Work in process	—	12
Finished goods	—	89
Total	$ —	$ 1,936

As noted in Note 2, the current economic environment along with the shift in business resulted in the Company reclassifying inventory to other current and long term assets as the Company has no intention to sell these assets but instead plans to use them for clinical trials. Additionally, the Company recorded an impairment charge of $0.1 million for the year ended December 31, 2020 related to certain excess inventory.

Other current assets consist of the following (in thousands):

	December 31,	
	2020	2019
Prepaid expenses	$ 599	$ 1,890
Insurance receivable	3,150	—
Other assets	181	69
Total	$ 3,930	$ 1,959

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2020	2019
Computer hardware	$ 261	$ 263
Computer software	274	291
Leasehold improvements	427	497
Furniture and fixtures	179	247
Scientific equipment	2,013	1,999
Construction in progress, or CIP	407	110
	3,561	3,407
Less: accumulated depreciation	(2,604)	(2,326)
Total	$ 957	$ 1,081

Depreciation expense was $0.3 million and $0.4 million for the year ended December 31, 2020 and 2019, respectively. As noted in Note 2, the current economic environment along with the shift in business focus is an impairment triggering event for the other long-lived assets. This resulted in impairment and other charges of $1.3 million for the year ended December 31, 2020. Based upon the Company's analysis, no other asset impairment charge was recorded.

Other current liabilities consist of the following (in thousands):

	December 31,	
	2020	2019
Accrued legal and professional fees	$ 529	$ 412
Accrued customer incentives	—	198
Accrued litigation	3,150	—
Accrued sales and other taxes	—	107
Returns reserve liability	—	315
Other accrued expenses	123	492
Total	$ 3,802	$ 1,524

Insurance Refund

During the year ended December 31, 2020, the Company received a refund pertaining to its Directors and Officer's Insurance for reimbursement of approximately $0.6 million. The refund related to excess charges regarding past insurance premiums. The full amount of the refund of $0.6 million was received during the year ended December 31, 2020 and was recorded as an offset to the Company's insurance expenses within selling, general and administrative expenses on the Company's consolidated statement of operations.

6. Debt

In June 2013, the Company entered into a $3.0 million loan and security agreement (the "Loan Agreement") with Square 1 Bank (predecessor-in-interest to Pacific Western Bank), which it subsequently amended in October 2014, September 2016, December 2016, June 2017 and July 2018.

In July 2018, the Company executed the Fifth Amendment to the Loan and Security Agreement (the "Loan Amendment") with Pacific Western Bank, which increased the loan capacity to $20 million from $10 million. The loan capacity of $20 million consists of two tranches as follows: a first tranche consisting of $10.0 million funded on July 10, 2018, of which the full $10.0 million was required to settle the existing debt with Pacific Western Bank on a net settlement basis (pursuant to its original terms); and a second tranche consisting of an additional $10.0 million which may be drawn at any time prior to July 9, 2019. During the first quarter of 2019, the Company drew down on the remaining $10.0 million tranche. During the second quarter of 2019, the Company paid down $15.0 million of the principal balance due under the Loan Agreement. During the third quarter of 2019, the Company paid down the remaining $5.0 million of principal balance due under the term loan, thereby removing the risks and restrictions of carrying long-term debt. As of December 31, 2020, the Company had no outstanding borrowings under the Loan Agreement.

The debt that was repaid in the third quarter of 2019 had a variable annual interest rate equal to the greater of the prime rate plus 1.5% per annum, or 5%, and would have matured in July 2022. While the debt was outstanding in 2019, the prime rate was 5.5%, resulting in an interest rate on the debt of 7.0% at the time that the Company paid down the remaining debt. The Loan Amendment provided for an interest-only period through July 9, 2019 followed by 36 equal monthly installments of principal and interest with the first principal payment due on August 9, 2019. Under the terms of the Loan Agreement, the Company could prepay the debt in full at any time with no additional cost, which occurred in August 2019.

Upon repayment of the outstanding debt in full, the Loan Agreement was terminated and the Company is no longer subject to the covenants and restrictions set forth in the Loan Agreement. The loan fee paid and the remaining balance of debt issuance costs and debt discount on the previous loan agreement held with Pacific Western Bank were amortized to interest expense during the third quarter of 2019. As of December 31, 2019, there were no unamortized debt issuance costs due to the $15.0 million and $5.0 million payments on the Company’s term loan in the second and third quarters of 2019, respectively.

Payroll Protection Program Loan

On April 22, 2020, the Company executed a promissory note (the "Note") with Silicon Valley Bank (the "Lender") evidencing an unsecured loan in the aggregate principal amount of $0.4 million (the "PPP Loan"), which was made pursuant to the Paycheck Protection Program (the "PPP"). The PPP was established under the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), which was enacted on March 27, 2020, and is administered by the U.S. Small Business Administration ("SBA"). All the funds under the PPP Loan were disbursed to the Company on April 23, 2020.

The Note provides for a fixed interest rate of one percent per year with a maturity date of April 22, 2022 (the "Maturity Date"). Loan payments may be deferred until August 2021, which date is 10 months after the end of the Company's 24-week covered period for the PPP Loan. If the Company applies for loan forgiveness, loan payments may be deferred until the SBA remits the Company's loan forgiveness amount to the lender. As of December 31, 2020, the Company had not applied for loan forgiveness. The PPP Loan may be prepaid by the Company at any time prior to the Maturity Date with no prepayment penalties or premiums. The Note contains customary event of default provisions.

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loans granted under the PPP. Such forgiveness will be subject to approval by the SBA and the Lender and determined, subject to limitations, based on factors set forth in the CARES Act, including verification of the use of loan proceeds for payment of payroll costs and payments of mortgage interest, rent and utilities. In the event the PPP Loan, or any portion thereof, is forgiven, the amount forgiven is applied to outstanding principal. The terms of any forgiveness may also be subject to further regulations and guidelines that the SBA may adopt. The Company will carefully monitor all qualifying expenses and other requirements necessary to attain loan forgiveness; however, no assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. Also, under the terms of the CARES Act, upon a change of control, such as the proposed merger with ReShape Lifesciences, the Company must receive permission for the PPP loan to be transferred to the new Combined Company or repay the loan in full upon close of the transaction. If the Company does not obtain a waiver from Silicon Valley Bank prior to the consummation of the Merger, the full amount of principal and interest outstanding under the PPP loan could become due and payable upon the consummation of the Merger.

As of December 31, 2020, the Company has used all proceeds from the PPP Loan to retain employees, maintain payroll and make lease and utility payments.

7. Stock-Based Compensation

Equity Incentive Plans

On October 4, 2016, the 2016 Equity Incentive Plan, or the 2016 Plan, became effective. The 2016 Plan serves as a successor to the 2008 Plan. The 2016 Plan permits the award of stock options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards, cash awards and stock bonuses. The Company reserved 5,337 shares of common stock for issuance as of January 1, 2020 under the 2016 Plan. The number of shares reserved for issuance under the 2016 Plan increases automatically on January 1 of each calendar year continuing through the tenth calendar year during the term of the 2016 Plan by the number of shares equal to 4% of the total outstanding shares of the Company's common stock and common stock equivalents as of the immediately preceding December 31. On December 31, 2020, 163,512 shares remained available for future grant under the 2016 Plan.

The Company determines the fair value of each stock option or award on the grant date and recognizes that fair value as stock-based compensation straight-line over the vesting term of the award. The Company estimates forfeitures at the time of grant based on historical data and records stock-based compensation only for options and awards expected to vest. The Company revises its forfeiture estimates on an at least annual basis and records any difference as a cumulative adjustment in the period the estimates are revised.

The Company recorded total non-cash compensation, including non-cash compensation to employees and nonemployees in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year ended December 31,	
	2020	2019
Cost of revenue	$ —	$ (21)
Research and development	276	739
Selling, general and administrative	813	2,265
Total	$ 1,089	$ 2,983

Unrecognized stock-based compensation expense at December 31, 2020 for all stock-based compensation pertaining to options was approximately $0.6 million. Expense associated with all stock-based compensation is expected to be recognized over a weighted-average term of 2.43 years.

Incentive Stock Options

Recipients of incentive stock options can purchase shares of the Company's common stock at a price equal to the stock's fair market value on the grant date, based on the closing price of the Company's stock on the grant date. Options granted generally expire after 10 years. Options granted generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years, subject to continued employment.

The fair value of each option granted was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

	Year ended December 31,	
	2020	2019
Assumed risk-free interest rate (1)	0.38% - 0.44% %	1.67% - 2.58 %
Assumed volatility (2)	69.86% - 70.84 %	55.07% - 65.21 %
Expected option life (3)	6.10 years	6.1 years
Expected dividend yield (4)	— %	— %

(1) The risk-free interest rate was determined based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.

(2) The volatility was determined based on analysis of the volatility of a peer group of publicly traded companies as the Company's stock has not traded publicly for a significant time and the Company has limited company specific historical volatility. The peer group was determined considering factors such as stage of development, risk profile, enterprise value and position within the industry.

(3) The expected option life was determined using the "simplified method" for estimating the expected option life, which is the average of the weighted-average vesting period and contractual term of the option.

(4) The expected dividend yield was zero as the Company has not historically issued dividends and does not expect to do so in the foreseeable future.

The following table summarizes stock option transactions for the 2016 Plan for the year ended December 31, 2020.

(in thousands, except shares and per share data):

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2019	518,468	38.64 39.42	6.8	12
Options granted	790,000	0.79		
Options exercised	—	—		
Options canceled	(208,613)	37.74		
Outstanding at December 31, 2020	1,099,855	$ 11.97	8.70	$ —
Vested and expected to vest at December 31, 2020	1,099,855	$ 11.97	8.70	$ —
Vested and exercisable at December 31, 2020	357,787	$ 40.31	6.47	$ —

The weighted-average fair value of options granted during the year ended December 31, 2020 was $0.49. The intrinsic value of options exercised for the years ended December 31, 2020 and 2019 was $0.

All options outstanding under the previous 2008 Stock Plan, or the 2008 Plan are exercisable under the early exercise provisions of the 2008 Plan. Options granted under the 2008 Plan that are exercised prior to vesting are subject to repurchase by the Company at the original issue price and will vest according to the respective option agreement. There were no options early exercised for the years ended December 31, 2020 and 2019. For prior early exercised options, no shares remain unvested with an immaterial related liability recorded under other current liabilities on the Company's consolidated balance sheet as of December 31, 2020.

Restricted Stock Awards

The following table summarizes restricted stock award transactions for the year ended December 31, 2020:

	Number of awards	Weighted-average grant date fair value
Outstanding at December 31, 2019	29,524	$ 39.64
Awards granted	—	—
Awards released	(26,524)	36.03
Awards canceled	—	—
Outstanding at December 31, 2020	3,000	$ 71.50

The Company's current restricted stock awards vest 100% at various terms from the grant date, subject to continued employment. The fair-value of each restricted stock award is determined on the grant date using the closing price of the Company's common stock on the grant date. Unamortized expense of $0.1 million is expected to be recognized over a weighted-average period of 0.2 years.

Restricted Stock Units

The following table summarizes restricted stock unit transactions for the 2016 Plan for the year ended December 31, 2020:

	Number of shares	Weighted-average grant date fair value	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2019	55,574	$ 11.70	106
Awards granted	816,081	1.88	
Awards released	(47,761)	12.04	
Awards canceled	(823,894)	1.95	
Outstanding at December 31, 2020	—	$ —	$ —
Vested and expected to vest at December 31, 2020	—	$ —	$ —

The Company's current restricted stock units vest 100% at various terms from the grant date, subject to continued service. The fair-value of each restricted stock unit is determined on the grant date using the closing price of the Company's common stock on the grant date.

Employee Stock Purchase Plan

On October 5, 2016, the 2016 Employee Stock Purchase Plan, or ESPP, became effective. The 2016 ESPP was adopted in order to enable eligible employees to purchase shares of the Company's common stock at a discount. Purchases will be accomplished through participation in discrete offering periods. The Company reserved 74,520 shares of common stock for issuance under the 2016 ESPP as of January 1, 2020. The number of shares reserved for issuance under the 2016 ESPP increases automatically on January 1 of each calendar year beginning after the first offering date and continuing through the first ten calendar years by the number of shares equal to 1% of the total outstanding shares of our common stock and common stock equivalents as of the immediately preceding December 31.

The ESPP was suspended in 2019. There were no shares of common stock issued during the year ended December 31, 2020, and December 31, 2019 pursuant to the ESPP.

8. Stockholders' Equity

In June 2018, the Company amended its certificate of incorporation to reduce the authorized number of shares of common stock from 300,000,000 to 100,000,000.

Public Offering and related warrants

On August 1, 2019, the Company entered into an underwriting agreement with A.G.P./Alliance Global Partners, as underwriter, in connection with a public offering of the Company's securities, pursuant to which the Company issued and sold (i) 2,427,500 shares of common stock (including 412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of common stock ("Pre-funded Warrants"), (iii) accompanying warrants to purchase up to 3,234,375 shares of common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) ("Purchase Warrants") and (iv) an additional warrant to the underwriters for the purchase 37,500 shares of common stock ("Representative Warrant"). The offering was made pursuant to a registration statement on Form S-1. The offering closed on August 6, 2019 resulting in gross proceeds of approximately $15.4 million. The Company incurred $0.7 million of legal, accounting, and other fees related to the offering. The shares of common stock and accompanying Purchase Warrants were sold at a public offering price of $4.00 per share, the Pre-funded Warrants and accompanying Purchase Warrants were sold at a public offering of $3.999. The Purchase Warrants were immediately exercisable upon issuance, will expire on August 6, 2024 and have an exercise price of $4.40 and the Representative Warrant has an exercise price of $5.00, in each case subject to adjustment

in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events. The Representative Warrant is exercisable in February 2020 and expires on August 6, 2024. All of the Pre-funded warrants were exercised during the third quarter of 2020. None of the Purchase or Representative Warrants have been exercised as of December 31, 2020. All of the warrants are recorded within equity in accordance with authoritative accounting guidance.

Participation in Follow-on Offering

Certain of the Company's directors, senior management and stockholders, including entities affiliated with holders of 5% or more of our capital stock and certain of our directors, purchased an aggregate of 670,312 shares of our common stock and warrants to purchase shares of our common stock in our follow-on offering of common stock and warrants to purchase shares of our common stock in August 2019 at the same price and on the same terms as the other purchasers in the offering and not pursuant to any pre-existing contractual rights or obligations.

Securities Purchase Agreement

On May 23, 2019, the Company entered into a Securities Purchase Agreement with certain investors for the sale by the Company of 500,000 shares of the Company's common stock, par value $0.001 per share, at a purchase price of $6.00 per share. The closing of the sale of the shares under the Securities Purchase Agreement occurred on May 28, 2019. The Company incurred $0.4 million of legal, accounting and other professional fees related to the Securities Purchase Agreement. The aggregate gross proceeds for the sale of the shares were $3.0 million.

Equity Distribution Agreement

On December 27, 2018, the Company entered into the Equity Distribution Agreement (the "Equity Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which the Company may, from time to time, sell shares of its common stock, having an aggregate offering price of up to $10.0 million through Canaccord, as the Company's sales agent.

The Company pays Canaccord a commission of 3.0% of the gross proceeds from the sales of common stock sold pursuant to the terms of the Equity Distribution Agreement. The Equity Distribution Agreement also contains, among other things, customary representations, warranties and covenants by the Company and indemnification obligations of the Company and Canaccord as well as certain termination rights for both the Company and Canaccord. The Company has no obligation to sell any at-the-market ("ATM") shares under the Equity Distribution Agreement, and may at any time suspend solicitation and offers under the Equity Distribution Agreement. Until the aggregate market value of the Company's common stock held by non-affiliates, or public float, is greater than $75.0 million, the amount the Company can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Company's ATM program, is limited to an aggregate of one-third of its public float.

The Company incurred $0.2 million of legal, accounting and other professional fees related to the Equity Distribution Agreement. These amounts are included as deferred charges within other current assets on the Company's consolidated balance sheet as of December 31, 2019 and all were charged against paid-in capital upon receipt of proceeds from the sale of common stock under the Equity Distribution Agreement. As of December 31, 2019, the Company has sold 377,615 shares under the Equity Distribution Agreement for aggregate gross proceeds of $2.8 million.

Lincoln Park Purchase Agreement

On December 27, 2018, the Company entered into a purchase agreement (the "Lincoln Park Purchase Agreement") with the Lincoln Park Capital Fund, LLC ("Lincoln Park") and a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $20.0 million of the Company's common stock, over the 36-month period that commenced in February 2019.

Under the Lincoln Park Purchase Agreement, and excluding the impact of any adjustments resulting from the Company's reverse stock split, on any business day selected by the Company on which the closing price of its common stock is not less than $0.50 per share (subject to standard anti-dilution adjustments), the Company may direct Lincoln Park to purchase up to 50,000 shares of common stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 100,000 shares, provided that the closing sale price of the common stock is not below $2.00 on the purchase date (subject to standard anti-dilution adjustments) (ii) the Regular Purchase may be increased to up to 125,000 shares, provided that the closing sale price of the common stock is not below $3.00 on the purchase date (subject to standard anti-dilution adjustments) and (iii) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below $4.00 on the purchase date (subject to standard anti-dilution adjustments). In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The purchase price per share for each such Regular Purchase will be based off of prevailing market prices of the Company's common stock immediately preceding the time of sale without any fixed discount. In addition to Regular Purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Lincoln Park Purchase Agreement.

Depending on the prevailing market price of our common stock, the Company may not be able to sell shares to Lincoln Park for the maximum $20.0 million over the term of the Lincoln Park Purchase Agreement. For example, under the rules of the Nasdaq Capital Market, in no event may the Company issue more than 19.99% of its shares outstanding (which is approximately 465,470 shares based on 2,328,512 shares outstanding prior to the signing of the Lincoln Park Purchase Agreement) under the Lincoln Park Purchase Agreement unless the Company obtains stockholder approval or an exception pursuant to the rules of the Nasdaq Capital Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the exchange cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Lincoln Park Purchase Agreement is equal to or greater than the specified minimum amount set forth in the Lincoln Park Purchase Agreement. The Company is not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach its obligations under the rules or regulations of the Nasdaq Capital Market. In addition, Lincoln Park will not be required to purchase any shares of the Company's common stock if such sale would result in Lincoln Park's beneficial ownership exceeding 9.99% of the then outstanding shares of the Company's common stock. The Company's inability to access a portion or the full amount available under the Lincoln Park Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on its business.

The Company incurred $0.8 million of commitment shares issued, legal, accounting, registration and other professional fees related to the Lincoln Park Purchase Agreement. These amounts are included as deferred charges within other current assets on the Company's balance sheet as of December 31, 2019 and all were charged against paid-in capital upon receipt of proceeds from the sale of common stock under the Lincoln Park Purchase Agreement. As of December 31, 2019, the Company has sold 356,122 shares under the Lincoln Park Purchase Agreement for aggregate gross proceeds of $4.2 million. No future issuances will occur under this agreement.

On February 5, 2020, the Company entered into a new purchase agreement (the "Purchase Agreement") and registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $15.0 million of the Company's common stock, $0.001 par value per share (the "Common Stock"). The new Purchase Agreement replaces an existing purchase agreement, dated December 27, 2018, by and between the Company and Lincoln Park, pursuant to which Lincoln Park committed to purchase up to $20.0 million of the Company's Common Stock. In connection with entering into the new Purchase Agreement, the Company and Lincoln Park terminated the prior purchase agreement, effective February 5, 2020.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of the Company's Common Stock. Such sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on February 28, 2020 date that a registration statement covering the resale of shares of Common Stock that have been and may be issued under the Purchase Agreement, which the Company agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement, was declared effective by the SEC and a final prospectus in connection therewith was filed and the other conditions.

The Company incurred approximately $0.3 million of legal, accounting, and other fees related to the offering. As of December 31, 2020, the Company has not sold any shares under the Purchase Agreement to Lincoln Park. The Company determined that there is a low probability that the equity line will be utilized for the remainder of 2020 due to adverse market circumstances. As a result, the Company fully expensed the $0.3 million of fees in March 2020.

Blue Ox

On August 11, 2020, the Company entered into a consulting agreement (the "Consulting Agreement") with Blue Ox Healthcare Partners, LLC ("Blue Ox") and its assigned entities. Pursuant to the Consulting Agreement, Blue Ox worked to (i) secure an agreement between the Company and a major health plan to conduct an outcomes study that will expand the current clinical evidence base to include health economic analysis on the cost of care reductions from use of the Obalon Balloon System, (ii) advise the Company's management regarding the development of a coverage and reimbursement-based market strategy, and (iii) secure agreements with health plans and other entities that result in reimbursement for and/or utilization of the Obalon Balloon System, among other services. Pursuant to, and in accordance with, the terms and conditions of the Consulting Agreement, the Company issued to Blue Ox a warrant (the "Warrant') to purchase up to 100,000 shares of the Company's common stock, par value $0.001 per share, at an exercise price of $0.8285, subject to adjustment pursuant to the terms of the Warrant. The Warrant is exercisable immediately and will expire on August 10, 2025. The exercise price represents a 15% premium to the average closing price of the Company's common stock for the 10 days preceding the effective date of the Consulting Agreement. The Warrant may be exercised, in whole or in part, through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Warrant. If the Consulting Agreement is terminated within six months of the effective date of the Consulting Agreement, then the number of shares of common stock that may be purchased by Blue Ox under the Warrant shall be reduced on a pro rata basis. The Warrant was deemed to qualify for equity treatment under authoritative accounting guidance and an immaterial amount was recorded within equity on the Company's consolidated statement of stockholders' equity for the year ended December 31, 2020.

The Warrant provides for certain piggy back registration rights if, during the period beginning six (6) months after the date of the Consulting Agreement and ending six (6) months after the expiration date of the Warrant, the Company proposes to file a registration statement under the Securities Act of 1933, as amended, with respect an offering by the Company of its common stock (other than certain registration statements as set forth in the Warrant). The Company also agreed to grant Blue Ox certain additional warrants upon the completion of certain milestones. Any such warrants would have generally the same terms and conditions and exercise price as the Warrant. Pursuant to the Consulting Agreement, Blue Ox also has the right to participate in the first securities offering of the Company, if any, following the effective date of the Consulting Agreement, subject to certain limitations.

As of December 31, 2020, the Consulting Agreement has been terminated and is no longer in effect. The warrants remained outstanding and were subsequently fully exercised in the first quarter 2021.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2020:

Stock options issued and outstanding	1,099,855
Restricted stock units issued and outstanding	3,000
Warrants for the purchase of common stock	3,371,875
Authorized for future option and ongoing vesting of award grants	163,512
Authorized for future issuance under ESPP	190,222
Total	4,828,464

9. Income Taxes

The income tax provision consists of the following (in thousands):

	Year ended December 31,	
	2020	2019
Current:		
Federal	$ —	$ —
State	—	14
Total current provision	—	14
Deferred:		
Federal	—	—
State	—	—
Total deferred provision	—	—
Income tax provision	$ —	$ 14

The difference between income tax benefits and income taxes computed using the U.S. federal income tax rate as of December 31, 2020 and 2019 are as follows (in thousands):

	Year ended December 31,	
	2020	2019
Federal provision (benefit)		
At statutory rates	$ (2,525)	$ (4,971)
Uncertain tax positions	5,690	507
Other	(101)	(2,471)
Change in valuation allowance	(3,064)	6,949
Income tax provision	$ —	$ 14

Significant components of the Company's deferred tax assets and liabilities are as shown below (in thousands):

	Year ended December 31,	
	2020	2019
Deferred tax assets:		
Net operating losses	$ 37,777	$ 35,252
Tax credits	—	5,493
Capitalized research and development costs	1,864	2,401
Other	3,014	2,724
Total gross deferred tax assets	42,655	45,870
Less valuation allowance	(42,514)	(45,578)
Total deferred tax assets	$ 141	$ 292
Deferred tax liabilities:		
Other	$ (141)	$ (292)
Total deferred tax liabilities	$ —	$ —

A valuation allowance of $42.5 million and $45.6 million as of December 31, 2020 and 2019, respectively, has been established to offset the deferred tax assets as realization of such assets are uncertain.

At December 31, 2020, the Company had federal and state net operating loss carryforwards of approximately $157.4 million and $126.0 million, respectively. The federal and state tax loss carryforwards will begin expiring in 2028, unless previously utilized. The federal net operating loss carryover includes $69.2 million of net operating losses generated after 2017. Federal net operating losses generated in 2018 and beyond carryover indefinitely and may generally be used to offset up to 80% of future taxable income. The Company also has federal and California research and development tax credit carryforwards totaling $3.4 million and $2.7 million, respectively. The federal research and development tax credit carryforward will begin to expire in 2028 unless previously utilized. The California research tax credits do not expire.

Pursuant to Internal Revenue Code, or IRC, Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382 and 383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. The deferred tax asset associated with the Company's federal and state net operating losses are fully offset by a valuation allowance. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance.

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon an audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. As of December 31, 2020 and 2019, the Company had unrecognized tax benefits of $10.5 million and $4.3 million, respectively. There are no unrecognized tax benefits included on the consolidated balance sheet that would, if recognized, impact the effective tax rate, given the valuation allowance recorded against the deferred tax assets. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,	
	2020	2019
Balance at January 1	$ 4,250	$ 3,609
Additions based on tax positions related to current year	250	643
Additions based on tax positions related to prior years	6,049	—
Reductions for tax positions related to prior years	—	(2)
Balance at December 31	$ 10,549	$ 4,250

The Company is subject to taxation in the United States and various state jurisdictions. Due to the net operating loss carryforwards, the U.S. federal and state returns are open to examination for all years since inception. The Company has not been, nor is it currently, under examination by the federal or any state tax authority.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (Cares Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the provisions are the extension of the carryback period of certain losses to five years, and increasing the ability to deduct interest expense from 30 percent to 50 percent of modified taxable income. The CARES Act for a credit against employee wages, the opportunity to defer payment of a portion of federal payroll taxes to December 2021 and December 2022 and enhanced small business loans to assist business impacted by pandemic. The Company's tax provision and financial position was not materially impacted by the CARES Act.

On December 27, 2020, the United States enacted the Consolidated Appropriations Act which extended and modified many of the tax related provisions of the CARES Act. The Company does not anticipate an impact of the Consolidated Appropriations Act on its tax provision or financial position.

10. Commitments and Contingencies

Operating Leases

The Company leases its facilities and retail treatment center under noncancelable operating leases which expire on various dates between 2022 and 2025. In July 2019, the Company entered into an office lease agreement to launch an Obalon-branded retail treatment center in San Diego, California, which expires on August 5, 2021. In January 2020, the Company entered into lease agreements for two additional Obalon-branded retail treatment centers in Orange County, California and Sacramento, California, respectively. Under the terms of the facilities and retail center leases, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs. The treatment center leases in Sacramento and San Diego were terminated on April 29, 2020 and May 27, 2020, respectively as a result in the Company's shift in strategy away from the retail treatment center model in the second quarter of 2020. The Company has not paid rent under the Orange County lease but is current with its rent obligations under its lease for its headquarters in Carlsbad, since April 2020. The full amounts of the unpaid rent have been accrued on the Company's balance sheet as of December 31, 2020.

The Company's landlord in Carlsbad, Gildred Development Company ("Gildred"), has since sent a demand letter for rent. On October 13, 2020, Gildred served the Company with an unlawful detainer action in the Superior Court of California, County of San Diego (Gildred Development Company v. Obalon Therapeutics, Inc., Case No. 37-2020-00035927-CU-UD-CTL). Gildred alleges that the Company owes more than $113,000 of unpaid rent and fees to Gildred and seeks damages for unpaid rent and continued occupancy of the premises. On November 18, 2020, Gildred filed an ex parte application for a writ of attachment or, in the alternative, a temporary protective order. The application was denied on November 24, 2020. On December 28, 2020, Gildred filed another application for a writ of attachment or, in the alternative, a temporary protective order. On January 22, 2021, the court granted Gildred's application for a writ of

attachment. The Company paid the amount of the writ in full, which was $338,000, and the parties are working toward a resolution of the action.

During the year ended December 31, 2020, the Company recorded a $0.4 million charge to fully write off the Orange County right-of-use asset as the center will not be functioning.

Upon the Company's adoption of ASC 842 as of January 1, 2019, the Company recognized a ROU asset and lease liability for its building lease, assuming a 7.0% discount rate. Any short-term leases defined as 12 months or less or month-to-month leases were excluded and continue to be expensed each month. Total costs associated with short-term leases for the year ended December 31, 2020 were immaterial.

The Company determines if an arrangement is a lease at inception. The exercise of lease renewal options is at the Company's sole discretion and were not included in the calculation of the Company's lease liability as the Company is not able to determine without uncertainty if the renewal option will be exercised. The depreciable life of assets and leasehold improvements are limited to the expected term, unless there is a transfer of title or purchase option reasonably certain of exercise. The Company's lease agreements do not contain any variable lease payments, residual value guarantees or any restrictive covenants.

The Company's ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date of the lease or the ASC 842 adoption date, whichever is later, based on the present value of lease payments over the lease term. When readily determinable, the Company uses the implicit rate in determining the present value of lease payments, or 7.0%, as of the adoption date. When leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date or adoption date, including the lease term. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company recorded an immaterial amount of lease liabilities, ROU assets, and interest expense associated with finance leases as of and for the year ended December 31, 2020. The underlying asset utilized through the finance lease was purchased by the Company during the fourth quarter of 2020 and no further financing leases remained as of December 31, 2020. The current and long-term portions of operating lease liabilities are presented within the current portion of lease liabilities and lease liabilities long-term line items on the consolidated balance sheet, respectively. Operating lease ROU assets are presented within the lease right-of-use assets line item on the consolidated balance sheet.

Future minimum annual lease payments under such leases were as follows as of December 31, 2020 (in thousands):

Operating leases:	
2021	$ 564
2022	219
2023	105
2024	108
2025	61
Total undiscounted lease payments - operating leases	1,057
Less: imputed interest	(55)
Lease liability	1,002
Less: current portion of lease liability	(564)
Lease liability, less current portion	$ 438

As of December 31, 2020, the Company's remaining lease terms range from 1.2 to 4.5 years. Rent expense totaled and $0.7 million and $0.6 million for the year ended December 31, 2020 and 2019, respectively. The Company paid $0.2 million and $0.5 million of cash payments related to its operating lease agreement for the year ended December 31, 2020 and 2019, respectively. The Company's weighted average discount rate for leases as of December 31, 2020 was 6.0%.

Supplier Contracts

The Company enters into contracts in the normal course of business with clinical trial sites and clinical supply manufacturing organizations and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts.

Shareholder Lawsuit

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against us and certain of our executive officers in the United States District Court for the Southern District of California (Hustig v. Obalon Therapeutics, Inc., et al., Case No. 3:18-cv-00352-AJB-WVG, and Cook v. Obalon Therapeutics, Inc. et al., Case No. 3:18-cv-00407-CAB-RBB). On July 24, 2018, the court consolidated the lawsuits and appointed Inter-Local Pension Fund GCC/IBT as lead plaintiff. On October 5, 2018, plaintiffs filed an amended complaint. The amended complaint alleges that we and certain of our executive officers made false and misleading statements and failed to disclose material adverse facts about our business, operations, and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of the Company's initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation. On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims. On August 17, 2020, the parties submitted a final settlement agreement of the securities class action for court approval. A hearing on final settlement approval is scheduled for April 22, 2021. The settlement provides for a payment of $3.15 million to the plaintiffs, and provides that the defendants continue to deny the allegations and claims asserted by the plaintiffs, and are entering into the settlement solely to eliminate the burden and expense of further litigation. The Company expects that any amounts due as part of the settlement will be covered by the Company's insurance policies. As of December 31, 2020 the Company has recorded a $3.15 million liability within other current liabilities and a corresponding $3.15 million receivable within other current assets.

11. Variable Interest Entity

In conjunction with the Company's strategic focus to open weight loss treatment centers to provide medical services to patients who wish to lose weight through the Obalon balloon system, the Company entered into a consulting agreement with a lead doctor to open the first treatment center and oversee the treatment center's activities. The treatment center was opened in September 2019 as a professional corporation ("PC") in the State of California and, as a result of state regulatory requirements, may not be owned by a corporation. The Company will fully fund all the activities of the treatment center and no financial contribution will be made by the lead doctor. In addition, the Company is authorized and expected to provide daily oversight of the activities of the center, with the exception of directly providing medical services.

As the PC's equity investment at risk is not sufficient to permit the entity to finance its activities without subordinated financial support, the PC is considered a variable interest entity. Although the Company does not own any equity interest in the PC, the Company holds the controlling financial interest as the sole funding source for the entity and through the ability to provide daily oversight. Therefore, the Company was determined to be the primary beneficiary of the PC and consolidated the PC's balances and activity within its consolidated financial statements.

For the year ended December 31, 2020, the PC recognized $0.3 million of deferred revenue associated with prepaid services at the treatment center, which is fully presented in the consolidated balance sheet of the Company at December 31, 2020.

12. Restructuring Charges

2019 Restructuring Activities

In the second quarter of 2019, the Company recorded restructuring charges of $1.1 million, which are comprised of the following components (in thousands):

	Year Ended December 31, 2019
Employee separation costs	$ 1,008
Asset disposals	91
Total	$ 1,099

In April 2019, the Company notified approximately 49 employees whose employment will be terminated, or approximately 50% of its workforce, with the intent to refocus activities, streamline operations and make more efficient use of cash. As a result of the workforce reduction, the Company recorded a restructuring charge in April 2019 for termination benefits of $0.5 million which has been paid as of December 31, 2019. Additionally, as a result of the workforce reduction, the Company recognized a reversal of stock-based compensation expense of $0.8 million in April of 2019 and a $0.1 million restructuring charge in connection with the disposal of assets related to the terminated employees.

In May and June 2019, the Company accepted the voluntary resignations of its President and Chief Executive Officer and its Vice President of Research and Development. As part of the resignations, each former officer entered into a consulting agreement for a term of 12 months, which allows for the continuous vesting of stock awards held over the consulting term and a monthly, fixed consulting fee. No severance amounts were granted. The Company recorded a restructuring charge in June 2019 for the full consulting benefits of $0.6 million of which $0.6 million has been paid as of December 31, 2020. Additionally, the Company recognized the full stock-based compensation expense of $0.7 million for these two former officers.

No further restructuring charges were recorded in the third or fourth quarters of 2019. For the year ended December 31, 2019, the following restructuring charges were included in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31, 2019
Cost of revenue	$ 53
Research and development	370
Selling, general and administrative	676
Total	$ 1,099

Activity and restructuring charge reserve balance as of December 31, 2019 were as follows (in thousands):

	Employee separation costs
Reserve balance at December 31, 2018	$ —
2019:	
Restructuring charges	1,099
Cash payments	(819)
Reserve balance at December 31, 2019	$ 280

As of December 31, 2020, all payments were made and the reserve was reduced to zero.

13. Subsequent Events

Merger Agreement

On January 19, 2021, The Company, Optimus Merger Sub, Inc., a Delaware corporation, and a direct, wholly owned subsidiary of the Company ("Merger Sub"), and ReShape Lifesciences, Inc., a Delaware corporation ("ReShape"), entered into an Agreement and Plan of Merger (the "Merger Agreement"). Pursuant to the Merger Agreement, and subject to the satisfaction or waiver of the conditions specified therein, Merger Sub shall be merged with and into ReShape, with ReShape surviving as a wholly owned subsidiary of Obalon (the "Merger").

Merger Consideration

At the effective time of the Merger (the "Effective Time"), each share of common stock, par value $0.001 per share, of ReShape ("ReShape Common Stock") and each share of Series B Preferred Stock, par value $0.01 per share, of ReShape (together with ReShape Common Stock, "ReShape Shares") issued and outstanding immediately prior to the Effective Time (other than the shares that are owned by Obalon, ReShape, or Merger Sub) will be 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 (an "Obalon Share") according to a ratio determined at least 10 days prior to the Obalon Stockholders' Meeting that will result in the holders of such ReShape Shares owning 51% of the outstanding Obalon Shares immediately after the Effective Time (such ratio, the "Exchange Ratio").

Treatment of Equity

The Merger Agreement provides that, at the Effective Time, each outstanding warrant to purchase capital stock of ReShape ("ReShape Warrant") will be converted into warrants to purchase a number of Obalon Shares equal to the number of shares of ReShape Common Stock issuable upon exercise of such ReShape Warrant multiplied by the Exchange Ratio with an exercise price equal to the exercise price of such ReShape Warrant divided by the Exchange Ratio. In addition, each outstanding option to purchase ReShape Common Stock, whether vested or unvested, ("ReShape Option") shall be cancelled and terminated without any payment. The Company will assume the obligations of the Series C Preferred Stock, par value $0.01 per share of ReShape ("ReShape Series C Preferred Stock") and shall file a new certificate of designation with the same terms and conditions as the ReShape Series C Certificate of Designation. Each outstanding option to purchase Obalon Shares and each outstanding restricted stock unit granted under an Obalon equity plan will become fully vested at the Effective Time.

Governance

The Merger Agreement provides that as of the Effective Time, the Company will be renamed ReShape Lifesciences Inc. (the "Combined Company") and the five current directors of ReShape will be comprise the board of directors of the Combined Company: Dan W. Gladney, Barton P. Bandy, Arda M. Minocherhomjee, Ph.D., Lori C. McDougal and Gary D. Blackford. Mr. Gladney will serve as the chairperson and Mr. Blackford will serve as lead director of the board of directors. As of the Effective Time, Mr. Bandy will serve as chief executive officer and Tom Stankovich will serve as the chief financial officer of the Combined Company.

Conditions to the Merger

The consummation of the Merger is subject to customary closing conditions, including (i) approval of the issuance of Obalon Shares in connection with the Merger by the affirmative vote of the majority of Obalon Shares cast at the Obalon Shareholders' Meeting in favor of the issuance of Obalon Shares in connection with the Merger, (ii) the adoption of the Merger Agreement by the affirmative vote of the holders of a majority of all outstanding shares of ReShape common stock entitled to vote thereon, (iii) the absence of any law or order by any governmental entity in effect that seeks to enjoin, make illegal, delay or otherwise restrain or prohibits the consummation of the Merger, (iv) Nasdaq's approval of the Obalon Shares to be issued in the Merger being listed on the Nasdaq, (v) Nasdaq's approval of the continued listing application for the Combined Company to maintain the Company's Nasdaq listing, (vi) subject to certain materiality exceptions, the accuracy of certain representations and warranties of each of Obalon and ReShape contained in the

Merger Agreement and the compliance by each party with the covenants contained in the Merger Agreement, (vii) the absence of a material adverse effect with respect to each of the Company and ReShape and (viii) the registration statement registering the merger consideration becoming effective.

Issuance of Common Stock

From January 1, 2021 through March 2, 2021, the Company's warrant holders covering 2.3 million shares exercised the warrants and common stock was issued in exchange for proceeds of $9.5 million.

ITEM 16. Form 10-K Summary

None.

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 hereunto duly authorized.

OBALON THERAPEUTICS, INC.

Date: March 12, 2021 by: /s/ Andrew Rasdal
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 12, 2021 by: /s/ Nooshin Hussainy
Chief Financial Officer
(Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrew Rasdal and Nooshin Hussainy as his or her true and lawful attorneys-in-fact, and each of them, with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, and either of them, or his or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Andrew Rasdal **Andrew Rasdal**	President and Chief Executive Officer and Director (Principal Executive Officer)	Date: March 12, 2021
/s/ Nooshin Hussainy **Nooshin Hussainy**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	Date: March 12, 2021
/s/ Kim Kamdar, Ph D. **Kim Kamdar, Ph D.**	Chairperson of the Board	Date: March 12, 2021
/s/ William Plovanic **William Plovanic**	Director	Date: March 12, 2021
/s/ Ray Dittamore **Ray Dittamore**	Director	Date: March 12, 2021
/s/ Douglas Fisher, M.D. **Douglas Fisher, M.D.**	Director	Date: March 12, 2021
/s/ Les Howe **Les Howe**	Director	Date: March 12 2021
/s/ Sharon Stevenson, DVM Ph D. **Sharon Stevenson, DVM Ph D.**	Director	Date: March 12, 2021

INDEX TO EXHIBITS

Exhibit Number	Description of Document	Form	Exhibit Filing Date	Exhibit	Filed/Furnished Herewith
1.1	Equity Distribution Agreement, dated December 27, 2018, between Obalon Therapeutics, Inc. and Canaccord Genuity LLC	8-K	12/27/18	1.1	
2.1	Agreement and Plan of Merger, dated as of January 19, 2021, by and among Obalon Therapeutics, Inc., ReShape Lifesciences Inc. and Optimus Merger Sub Inc.	8-K	1/20/01	2.1	
3.1	Restated Certificate of Incorporation	S-1	9/26/16	3.2	
3.2	Certificate of Amendment to the Restated Certificate of Incorporation	8-K	6/14/18	3.1	
3.3	Certificate of Second Amendment to the Restated Certificate of Incorporation	8-K	7/24/19	3.1	
3.4	Restated Bylaws	S-1	9/26/16	3.4	
4.1	Form of Common Stock Certificate	S-1	9/9/16	4.1	
4.2	Form of Amended and Restated Investors' Rights Agreement dated April 29, 2016 among the Registrant and certain of its stockholders	S-1	9/9/16	4.2	
4.4	Amended and Restated Warrant to Purchase Stock issued to Square 1 Bank to purchase shares of Series C-1 Preferred Stock, issued June 14, 2013, as amended October 1, 2014.	S-1	9/9/16	4.4	
4.5	Second Warrant to Purchase Stock issued to Square 1 Bank to purchase shares of Series D Preferred Stock, dated October 1, 2014.	S-1	9/9/16	4.5	
4.6	Securities Purchase Agreement by and among Obalon Therapeutics, Inc. and the investors signatory thereto, dated August 22, 2018	S-3	8/31/18	4.3	
4.7	Registration Rights Agreement by and among Obalon Therapeutics, Inc. and the investors signatory thereto, dated August 22, 2018	S-3	8/31/18	4.4	
4.8	Description of Registrant's Securities	10-K	2/27/20	4.8	
4.10	Form of Common Stock Purchase Warrant	S-1/A	8/1/19	4.6	
4.11	Form of Representative's Warrant	S-1/A	8/1/19	4.7	
10.1‡	Form of Indemnity Agreement by and between the Registrant and its directors and officers	S-1	9/26/16	10.1	
10.2‡	2008 Stock Plan and form of award agreements thereunder.	S-1	9/9/16	10.2	
10.3‡	Amended and Restated 2016 Equity Incentive Plan and form award agreements thereunder	10-Q	11/06/20	10.1	
10.5‡	2016 Employee Stock Purchase Plan and form of enrollment agreement	S-1	9/26/16	10.4	
10.6‡	Amendment to Obalon Therapeutics, Inc. 2016 Employee Stock Purchase Plan	8-K	5/4/18	10.1	
10.7‡	Obalon Therapeutics, Inc. Bonus Plan	S-1	9/26/16	10.11	
10.8‡	Obalon Therapeutics, Inc. Director Compensation Program	10-K/A	4/29/20	10.8	
10.9‡	Form of CEO Retention Agreement	10-Q	11/10/16	10.6	
10.10‡	Form of Executive Retention Agreement (Non-CEO)	10-Q	11/10/16	10.7	

10.11‡	Form of Non-Employee Director Option Agreement.	10-K	2/23/17	10.8	
10.12‡	Offer Letter dated June 9, 2008 between the Registrant and Andrew Rasdal	S-1	9/26/16	10.5	
10.13‡	Offer Letter dated June 16, 2008 between the Registrant and Mark Brister	S-1	9/26/16	10.6	
10.14‡	Offer Letter dated November 24, 2008 between the Registrant and Amy VandenBerg	S-1	9/26/16	10.7	
10.15‡	Offer Letter dated January 26, 2016 between the Company and William Plovanic	10-Q	5/10/17	10.1	
10.17‡	Form of Executive Retention Agreement (Non-CEO) (April 2018)	10-Q	5/10/18	10.1	
10.18	Leases dated October 3, 2011 and November 23, 2015 between the Registrant and Pleta & San Gal Trusts dba: Ocean Point Tech Centre, and related amendments.	S-1	9/9/16	10.8	
10.19	Amendment to Lease, dated January 30, 2017, by and between Pleta & San Gal Trusts dba: Ocean Point and Registrant.	10-K	2/23/17	10.13	
10.20	Fourth Amendment to Lease dated May 31, 2018 between Gildred Development Company, DBA Ocean Point and Obalon Therapeutics, Inc.	8-K	6/5/18	10.1	
10.21‡	Form of Restricted Stock Unit Award pursuant to the 2016 Equity Incentive Plan	10-K	2/27/20	10.28	
10.22‡*	Consulting Agreement dated May 20, 2019 between the Company and Kelly Huang	10-Q	7/24/19	10.1	
10.23‡*	Offer Letter dated May 26, 2019 between the Company and Robert MacDonald	10-Q	7/24/19	10.2	
10.24‡*	Offer Letter dated November 15, 2011 between the Company and Nooshin Hussainy	S-1	2/7/20	10.31	
10.25	Form of Securities Purchase Agreement	8-K	5/28/19	10.1	
10.26‡*	Form of Restricted Stock Unit Award Agreement (Share and Cash Settlement) pursuant to the 2016 Equity Incentive Plan	10-K	2/27/20	10.33	
10.27	Purchase Agreement, dated February 5, 2020, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	2/7/20	10.1	
10.28	Registration Rights Agreement, dated February 5, 2020, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	2/7/20	10.2	
10.29 ‡	Form of Stock Option Agreement (Cash Settlement)	10-Q	7/30/20	10.2	
10.30	Promissory Note, dated as of April 22, 2020, by and between Obalon Therapeutics, Inc. and Silicon Valley Bank	8-K	4/27/20	10.1	
10.31‡	Amended and Restated Retention Agreement, dated as of June 9, 2020, by and between Obalon Therapeutics, Inc. and Andrew Rasdal	10-Q	6/19/20	10.2	
10.32‡	Amendment and Restated Retention Agreement, dated as of January 18, 2021, by and between Obalon Therapeutics, Inc. and Andrew Rasdal				X
10.33‡	Amended and Restated Retention Agreement, dated as of June 9, 2020, by and between Obalon Therapeutics, Inc. and Nooshin Hussainy	10-Q	6/19/20	10.3	

10.34‡	Amendment to Amended and Restated Retention Agreement, dated as of January 18, 2021, by and between Obalon Therapeutics, Inc. and Nooshin Hussainy				X
10.35‡	Transition and Consulting Agreement, dated as of June 11, 2020, by and between Obalon Therapeutics, Inc. and Amy Vandenberg	10-Q	6/19/20	10.4	
10.36‡	Transition and Consulting Agreement, dated as of June 11, 2020, by and between Obalon Therapeutics, Inc. and Mark Brister	10-Q	6/19/20	10.5	
21.1	Subsidiaries of the Registrant.				X
23.1	Consent of Independent Registered Public Accounting Firm (BDO USA, LLP)				X
23.2	Consent of Independent Registered Public Accounting Firm (KPMG US LLP)				X
24.1	Power of Attorney. Reference is made to the signature page hereto.				
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1†	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

* Portions of this exhibit has been omitted pursuant to Regulation S-K, Item 601(a)(6).

† This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

‡ Management contract or compensatory plan or arrangement.

Exhibit 10.32

AMENDMENT TO
AMENDED AND RESTATED RETENTION AGREEMENT

This amendment (the "Amendment") is made and entered into effective as of January 18, 2021, by and between Obalon Therapeutics, Inc. (the "Company") and Andrew Rasdal ("Executive").

RECITALS:

A. The Company and Executive are parties to that certain Amended and Restated Retention Agreement effective as of June 9, 2020 (as may be amended from time to time, the "Retention Agreement").

B. The Company and Executive desire to amend the terms of the Retention Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the parties hereto agree as follows:

1. Section 2 of the Retention Agreement is hereby deleted in its entirety and replaced with the following:

"2. **Retention Payments and Benefits.**

(a) **Bonus Payment**. If Executive remains in continuous employment with the Company until immediately prior to the earlier of (i) the Closing and (ii) April 30, 2021 (such date, the "**Bonus Retention Date**"), then, subject to Sections 3, 7, and 8 below, the Company shall pay the Executive $250,000. Such payment shall be paid in a cash lump sum payment in accordance with the Company's standard payroll procedures, which payment will be made immediately prior to the Bonus Retention Date, *provided that* the Release Conditions have been satisfied.

(b) **Equity**. If Executive remains in continuous employment with the Company until immediately prior to the Closing then, upon the Closing, subject to Sections 3, 7, and 8 below, each of Executive's then-outstanding Equity Awards that vest based solely on the passage of time shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award. "**Equity Awards**" means all options to purchase shares of Company common stock, as well as any and all other stock-based awards granted to the Executive, including but not limited to stock bonus awards, restricted stock, restricted stock units or stock appreciation rights. Subject to Section 3, the accelerated vesting described above shall be effective as of immediately prior to the Closing. For clarity, any Equity Awards that vest only upon satisfaction of performance criteria ("**Performance Equity Awards**") shall continue to be governed by the vesting and acceleration provisions contained in the grant agreements for such Performance Equity Awards."

2. The penultimate sentence of Section 3 is hereby deleted in its entirety and replaced with the following:

"The Company will deliver the form of Release to the Executive on the Bonus Retention Date and the Closing, as applicable."

3. This Amendment shall be and, as of the date hereof, is hereby incorporated into and forms a part of, the Retention Agreement. The terms of the Retention Agreement not modified by this Amendment will remain in force and are not affected by this Amendment.

4. This Amendment will be governed and construed in accordance with the laws of the State of California, without reference to principles of conflict of laws. Capitalized terms used but not defined in this Amendment shall have the meanings ascribed to them in the Retention Agreement.

5. Original signatures transmitted and received via facsimile or other electronic transmission of a scanned document, (e.g., .pdf or DocuSign) are true and valid signatures for all purposes hereunder and shall bind the parties to the same extent as that of an original signature. This Amendment may be executed in multiple counterparts, each of which shall be deemed to constitute an original but all of which together shall constitute only one document.

IN WITNESS WHEREOF, the parties above have executed this Amendment as of the date first written above.

/s/ Andrew Rasdal
Andrew Rasdal

OBALON THERAPEUTICS, INC.

/s/ Raymond Dittamore
By: Raymond Dittamore
Director

Exhibit 10.34

AMENDMENT TO
AMENDED AND RESTATED RETENTION AGREEMENT

This amendment (the "Amendment") is made and entered into effective as of January 18, 2021, by and between Obalon Therapeutics, Inc. (the "Company") and Nooshin Hussainy ("Executive").

RECITALS:

A. The Company and Executive are parties to that certain Amended and Restated Retention Agreement effective as of June 9, 2020 (as may be amended from time to time, the "Retention Agreement").

B. The Company and Executive desire to amend the terms of the Retention Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the parties hereto agree as follows:

1. Section 2 of the Retention Agreement is hereby deleted in its entirety and replaced with the following:

"2. **Retention Payments and Benefits.**

(a) **Bonus Payment**. If Executive remains in continuous employment with the Company until immediately prior to the earlier of (i) the Closing and (ii) April 30, 2021 (such date, the "**Bonus Retention Date**"), then, subject to (A) Executive's satisfaction of the Release Conditions, (B) Executive's continued compliance with the terms and conditions of Section 4 of this Agreement, and (C) Sections 7 and 8 below, the Company shall pay the Executive $250,000. Such payment shall be paid in a cash lump sum payment in accordance with the Company's standard payroll procedures, which payment will be made immediately prior to the Bonus Retention Date.

(b) **Equity**. If Executive remains in continuous employment with the Company until immediately prior to the Closing then, upon the Closing, subject to (A) Executive's satisfaction of the Release Conditions, (B) Executive's continued compliance with the terms and conditions of Section 4 of this Agreement, and (C) Sections 7 and 8 below, each of Executive's then-outstanding Equity Awards that vest based solely on the passage of time shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award. "**Equity Awards**" means all options to purchase shares of Company common stock, as well as any and all other stock-based awards granted to the Executive, including but not limited to stock bonus awards, restricted stock, restricted stock units or stock appreciation rights. Subject to Section 3, the accelerated vesting described above shall be effective as of immediately prior to the Closing. For clarity, any Equity Awards that vest only upon satisfaction of performance criteria ("**Performance Equity Awards**") shall continue to be governed by the vesting and acceleration provisions contained in the grant agreements for such Performance Equity Awards."

2. The penultimate sentence of Section 3 is hereby deleted in its entirety and replaced with the following:

"The Company will deliver the form of Release to the Executive on the Bonus Retention Date and the Closing, as applicable."

3. This Amendment shall be and, as of the date hereof, is hereby incorporated into and forms a part of, the Retention Agreement. The terms of the Retention Agreement not modified by this Amendment will remain in force and are not affected by this Amendment.

4. This Amendment will be governed and construed in accordance with the laws of the State of California, without reference to principles of conflict of laws. Capitalized terms used but not defined in this Amendment shall have the meanings ascribed to them in the Retention Agreement.

5. Original signatures transmitted and received via facsimile or other electronic transmission of a scanned document, (e.g., .pdf or DocuSign) are true and valid signatures for all purposes hereunder and shall bind the parties to the same extent as that of an original signature. This Amendment may be executed in multiple counterparts, each of which shall be deemed to constitute an original but all of which together shall constitute only one document.

IN WITNESS WHEREOF, the parties above have executed this Amendment as of the date first written above.

/s/ Nooshin Hussainy
Nooshin Hussainy

OBALON THERAPEUTICS, INC.

/s/ Raymond Dittamore
By: Raymond Dittamore
Director

Exhibit 21.1

Obalon Therapeutics Inc.
Subsidiaries

Name	Jurisdiction of Incorporation
Obalon Center for Weight Loss, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Obalon Therapeutics, Inc.
Carlsbad, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-213988, 333-218482, 333-224864, 333-232759, 333-235876, and 333-236062), Form S-3 (Nos. 333-221264 and 333-227160), and Form S-1 (Nos. 333-229142, 333-232276, and 333-236327) of Obalon Therapeutics, Inc. ("Company") of our report dated March 12, 2021, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP
Costa Mesa, California

March 12, 2021

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Obalon Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-213988, 333-218482, 333-224864, 333-232759, 333-235876,333-236062, and 333-252689) on Form S-8, (Nos. 333-221264 and 333-227160) on Form S-3, and (Nos. 333-229142, 333-232276, and 333-236327) on Form S-1 of Obalon Therapeutics, Inc. of our report dated February 27, 2020, with respect to the consolidated balance sheet of Obalon Therapeutics, Inc. as of December 31, 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2019, and the related notes, which report appears in the December 31, 2020 annual report on Form 10 K of Obalon Therapeutics, Inc. Our report dated February 27, 2020 contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and has a net capital deficiency, which raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

San Diego, California
March 12, 2021

Exhibit 31.1

Obalon Therapeutics, Inc.
Certification of Chief Executive Officer

Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Andrew Rasdal, certify that:

1. I have reviewed this Annual Report on Form 10-K of Obalon Therapeutics, 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 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.

Date: March 12, 2021

/s/ Andrew Rasdal
Andrew Rasdal
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Obalon Therapeutics, Inc.
Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Nooshin Hussainy, certify that:

1. I have reviewed this Annual Report on Form 10-K of Obalon Therapeutics, 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 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.

Date: March 12, 2021

/s/ Nooshin Hussainy
Nooshin Hussainy
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Obalon Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Andrew Rasdal the President and Chief Executive Officer, and Nooshin Hussainy, the Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his and her knowledge:

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

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

Dated: March 12, 2021

/s/ Andrew Rasdal	/s/ Nooshin Hussainy
Andrew Rasdal	Nooshin Hussainy
President and Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Obalon Therapeutics, Inc. and will be retained by Obalon Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. These certifications will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor will these certifications be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates them by reference.