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, 2019
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	**26-1828101**
(State of Incorporation)	**(I.R.S. Employer Identification No.)**
5421 Avenida Encinas, Suite F **Carlsbad, California**	**92008**
(Address of Principal Executive Offices)	**(Zip Code)**

(844) 362-2566
(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 S
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 S
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 S 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 and post such files). Yes S 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	S	Smaller reporting company	S
		Emerging growth company	S

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 financing accounting standards provided pursuant to Section 13(a) of the Exchange Act. S

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $16.6 million, based on the closing price of the Registrant's common stock of $0.70 as reported by The NASDAQ Global Market as of June 28, 2019. 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 1,190,777 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 February 18, 2020 was 7,731,633 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 2020 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

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: a favorable safety profile, improved patient tolerability and comfort, progressive weight loss with durable results, simple and convenient placement, and potentially attractive economics for patients.

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, reversible and repeatable weight loss solution in an outpatient setting, without altering patient anatomy or requiring surgery.

The current generation of our 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; 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. 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 progressive weight loss with durable results. In our 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 addition, patients in the Obalon treatment group showed, on average, progressive weight loss over the entire six-month balloon treatment period, and maintained, on average, 89.5% of the weight loss six months after balloon removal.

Data presented from our commercial registry demonstrates greater weight loss in the commercial setting as compared to clinical studies. In December 2018, data from our commercial registry was analyzed on more than 1,300 patients at 108 treatment sites. For

those patients who received three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in 9.9% reduction in total body weight and a 3.5 point decrease in BMI compared to baseline values. Of note, the top quartile of those patients lost an average of 39 pounds, resulting in a 16.8% reduction in total body weight and a 6.2 point decrease in BMI compared to baseline values. Furthermore, in May 2019, analysis of data from our commercial registry was updated to include 1,411 total patients from 143 treatment sites in the United States. In this larger 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. Weight loss in the first months of therapy was the largest predictor of success.

Current treatment alternatives for obese patients begin with lifestyle modification, such as diet and exercise. If this alternative fails to produce the desired results, physicians may prescribe pharmaceutical therapies, typically to obese or overweight patients with a lower BMI. Although pharmaceutical therapies have been effective in assisting with weight loss, they are often associated with safety risks and negative side effects that may limit patient compliance. In obese patients with a higher BMI, physicians may pursue aggressive surgical treatments, such as gastric bypass and gastric banding. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size; however, they present substantial side effects and carry short- and long-term safety risks that therefore have limited adoption. Intragastric balloons were first introduced in 2015 and represent a relatively new category of treatment for weight loss in the United States. We believe traditional liquid-filled intragastric balloons suffer from limitations that have impeded their adoption, including their rate of serious adverse device events, a lack of comfort and tolerability, a limited ability to provide progressive and sustained weight loss and an inconvenient placement procedure. We believe the Obalon Balloon System addresses many of these limitations and provides the foundation for an important, growing and sustainable treatment for weight loss.

We commenced U.S. commercialization of our prior generation Obalon balloon system in January 2017. In February 2019, we commercialized our current generation Obalon Balloon System with the Obalon Touch Inflation Dispenser and the Obalon Navigation System, which together are designed to make balloon placement more reliable, safer, easier and less expensive. The Obalon Navigation System is designed to eliminate the need to use x-ray technology when placing the Obalon balloon.

When we commenced commercial operations, we relied on a direct sales force to sell our products directly to physicians, who would then sell weight loss treatment packages to their patients that included our balloon therapy, dietary counseling and balloon removal on a non-reimbursed, self-pay basis. In 2019, we began implementing a fundamental change to our commercialization efforts, pursuant to which we would establish Company-owned or managed Obalon-branded retail treatments centers. The transition commenced with the elimination of our direct sales force in connection with an overall workforce reduction in April 2019. Concurrent with that reduction, we transitioned to a centralized customer support model through which we sell to existing physician customers or new physicians that contact us directly to acquire our system and balloons and provide marketing and clinical support to those physicians. Marketing support may include media assets and leads generated from our Find-A-Doc locater and leads generated from our digital and off-line marketing efforts.

In September 2019, the first Company-managed Obalon-branded, Obalon Center for Weight Loss™, opened, in San Diego, California. In February 2020, a second Obalon-managed Obalon Center for Weight Loss opened in Orange County, California. At these Company-managed retail treatment centers, patients can be prescribed and received treatment with the Obalon Balloon System. Each treatment center is wholly-owned by a physician through a separate professional entity. As manager of the facility, we provide the office support, non-clinical staff, equipment, marketing support, and other administrative services to the center where patients receive the Obalon balloon therapy from licensed physicians. We intend to manage additional Obalon Centers for Weight Loss and, where permissible under state law, to open Company-owned treatment centers, where we would directly employ or contract with physicians and other healthcare professionals who prescribe and administer the treatments. We believe this model will contribute to standardization of both quality of care and patient pricing, and provide us greater operational and financial control of our business.

THE OBESITY EPIDEMIC

Obesity has been identified by the U.S. Surgeon General as an epidemic and a significant threat to the quality of life in the United States. Based on results from the 2013-2014 National Health and Nutrition Examination Survey, it is estimated that more than 88 million adults in the United States were obese, defined as a BMI of 30 or greater, of which approximately 18 million were considered extremely obese with a BMI of 40 or greater, and approximately 76 million adults in the United States were overweight, defined as a BMI between 25 and 29.9. Research sponsored by the Centers for Disease Control and Prevention, or CDC, suggests that if current obesity rates persist, half of the U.S. population will be obese by 2030. Obesity is also a significant health problem outside of the United States. The number of obese adults worldwide has nearly tripled since 1975, and the World Health Organization estimates that more than 650 million adults were obese and more than 1.9 billion were overweight in 2016.

The CDC has identified obesity as a leading cause of preventable death in the United States, and it is one of the leading causes of chronic diseases both worldwide and in the United States. Obesity-related disorders, known as comorbidities, include cardiovascular

diseases, diabetes, musculoskeletal disorders and some cancers. The national medical care costs of obesity-related illness in adults, including out-of-pocket expenses, third-party payer expenses and Medicaid, were estimated to be up to $210 billion in 2008. Furthermore, in 2014 the annual global economic impact of obesity was estimated to be $2 trillion.

We expect the obesity epidemic among adults to continue to grow worldwide given the excess caloric intake of highly-processed, fatty foods, increasingly sedentary lifestyles and a growing prevalence of obesity among children and adolescents. Despite the growing public interest in the obesity epidemic and the significant medical and economic repercussions associated with the disease, there remains a significant unmet need for more effective treatments.

CURRENT TREATMENTS AND LIMITATIONS

Current treatment alternatives for patients who are obese and overweight begin with lifestyle modification, such as diet and exercise. If this course of treatment fails to produce the desired results, physicians may prescribe pharmaceutical therapies, and in patients with more severe obesity, physicians may pursue aggressive surgical treatments, such as gastric bypass and gastric banding. These approaches are associated with safety concerns, lifestyle impact and ease of use, cost and compliance issues that have limited their adoption. Additionally, some patients may seek to address the symptoms of weight-gain through the use of aesthetic products, certain of which have been approved for individuals with a BMI of 30 or less. We believe these aesthetic products only treat the symptoms and not the underlying disease. They are also not indicated for patients with obesity.

Lifestyle modification

Lifestyle modification, which includes diet, exercise and behavior modification, is usually prescribed as an initial treatment for a patient who is obese or overweight and is typically prescribed in all obesity management approaches. However, lifestyle modification alone has generally been ineffective in producing sustainable weight loss in patients with obesity due to inability to comply with the modifications over an extended period. Many studies have shown that a significant majority of dieters will regain lost weight and many will gain more than they originally lost.

Pharmaceutical therapy

Several pharmaceutical products have been approved by the FDA for obesity in the United States. Pharmaceutical therapy often represents a first option in the treatment of patients with obesity that have failed to achieve weight loss goals through lifestyle modifications alone. Pharmaceutical therapy can have limited effectiveness due to patient non-compliance. Additionally, pharmaceutical therapy may carry significant safety risks and negative side effects, such as adverse gastrointestinal, cardiovascular and central nervous system issues, some of which are serious or life threatening.

Bariatric surgery

Bariatric surgery is a treatment option generally reserved for cases of severe obesity, or patients with a BMI in excess of 40. The most common forms of bariatric surgery, gastric bypass and sleeve gastrectomy, promote weight loss by surgically restricting the stomach's capacity and outlet size. Gastric bypass also affects weight loss by restricting the body's ability to absorb nutrients. While largely effective, these procedures are generally invasive, expensive for the patient and irreversible. Bariatric surgery patients are generally required to make significant postoperative lifestyle changes, including strict dietary changes, vitamin supplementation and long-term medical follow-up programs. Side effects of bariatric surgery include a high rate of re-operation, nausea, vomiting, dumping syndrome, dehydration, dental problems and other issues.

Recently developed treatment alternatives

Given the shortcomings and limitations of the existing treatment alternatives, new medical procedures have been recently introduced in an attempt to address the gap in care between pharmaceutical treatment and invasive surgical procedures. These new procedures include: neuroblocking therapy, aspiration therapy and liquid-filled intragastric balloons. Neuroblocking therapy involves a surgical procedure in which a neuromodulation device is implanted in the body and used to block electrical signals from the stomach to the brain. By blocking those signals, the device attempts to control the patient's feelings of hunger. Aspiration therapy involves a surgical procedure in which a feeding tube is implanted in the abdomen in order to remove food from the stomach before calories are absorbed into the body. We believe high costs, procedural complications and the risk of SADEs may limit their adoption.

Intragastric balloons are a type of space-occupying device placed in the stomach in order to cause a sensation of fullness. Currently marketed traditional balloons are large, liquid-filled silicone devices that are placed in the stomach endoscopically, under anesthesia, for a treatment period of up to six months. Following treatment, the balloons are removed in a second endoscopic procedure. The only approved and marketed traditional liquid-filled intragastric balloons in the United States is the ORBERA® Balloon. While generally effective in delivering weight loss, traditional liquid-filled intragastric balloons have been accompanied by a number of limitations that have impeded their adoption, including: high rate of SADEs, lack of comfort and tolerability, limited ability to provide progressive and sustained weight loss, and inconvenient placement procedure.

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. As of December 31, 2019, 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 December 2018, we analyzed data from commercial registry on more than 1,300 patients at 108 treatment sites. For those patients who received three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in 9.9% reduction in total body weight. Furthermore, in May 2019, we updated the analysis of data from our commercial registry to include 1,411 total patients from 143 treatment sites in the United States. In this larger 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.

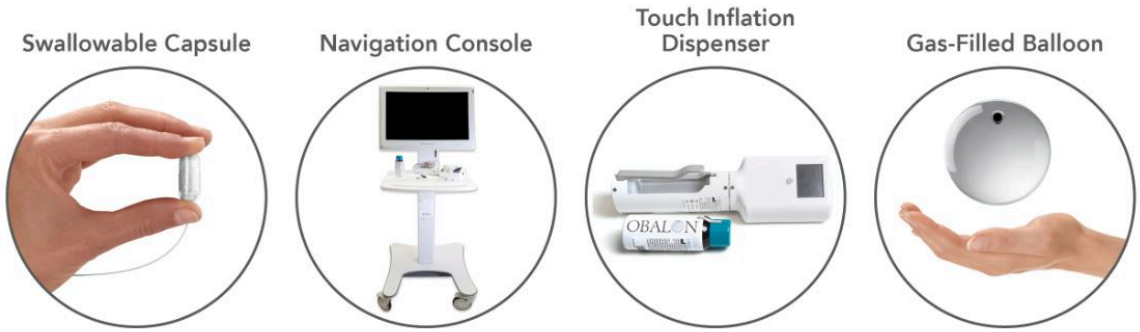
OUR STRATEGY

Our objective is to be the leading provider of medical devices for the non-surgical treatment of persons with obesity. The key elements of our strategy are to:

- ***Expand a Company-owned or managed Obalon branded retail treatment center commercialization model.*** In 2019 we transitioned our primary focus from selling directly to physicians to a new retail treatment center model, pursuant to which we plan to establish Company-owned or managed Obalon branded treatment centers where our products can be prescribed by physicians and administered to patients. We opened the first Company-managed Obalon-branded retail treatment center in September 2019 in San Diego, California, and a second Company-managed treatment center in February 2020 in Orange County, California. The Company-managed treatment centers are wholly-owned by a physician through a separate professional entity. As manager, we provide the office support, non-clinical staff, equipment, marketing support, and other administrative services to the center. Where permissible under state law, we plan to open Company-owned treatment centers, where we would directly employ or contract with physicians and other healthcare professionals who prescribe and administer the treatments. We believe this model will allow us to standardize both quality of care and patient pricing, and provide us greater operational and financial control of our business. We intend to continue pursuing this new commercialization model, with the goal of establishing additional centers in 2020.
- ***Continue to drive patient awareness and interest.*** We intend to drive patient awareness and interest in part through multiple efforts that may vary over time and may include digital, offline and social marketing. In addition, in the fourth quarter of 2018, we further enhanced our capabilities to convert patient interest to treatment by implementing the Obalon Ambassador Center. The Ambassador Center is focused on converting patient interest generated from our marketing efforts into booked appointments with the Obalon Center for Weight Loss™ treatment centers. We believe our Obalon-managed treatment centers will be able to directly leverage both our marketing capabilities and in-house call center to enhance the patient experience, from initial interest through to the completion of patient therapy.
- ***Strive to optimize manufacturing to drive operating leverage.*** We have built a highly leverageable manufacturing facility at our headquarters in Carlsbad, California, where we design, develop and manufacture 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. We believe we have the ability to increase our manufacturing scale for our current products within our current facility in a cost-effective manner.
- ***Protect and expand 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 have an inventive culture and expect to continue innovating to create a proprietary pathway for future product development. We intend to aggressively protect and enforce our intellectual property, both for existing and new products.

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 radiopaqued 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

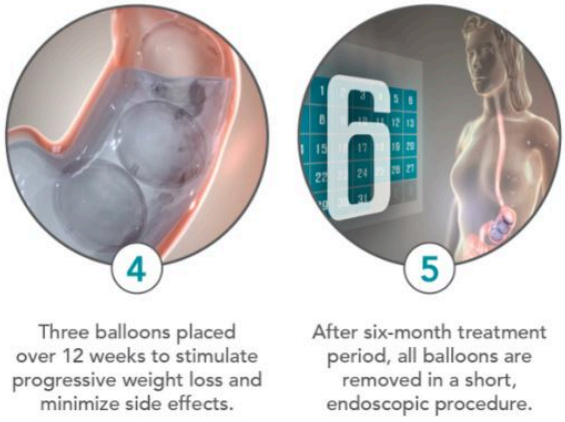
The Obalon Navigation System consists of a Navigation console and the Obalon Touch Inflation Dispenser. The Obalon Navigation System console is a portable device consisting of hardware and software that are used to track and display the Obalon balloon during administration. The Obalon balloon is placed 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 typically requires approximately 15 minutes on average.

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



Additional Product Under Development

We are developing a balloon intended for a longer duration of treatment, potentially up to one year. In our SMART trial, patients in the Obalon treatment group continued, on average, to lose weight throughout the six months of balloon treatment. We have completed the initial engineering and animal testing on the proprietary materials and systems, which we believe would permit reliable balloon performance over a longer period of up to twelve months. We intend to study if longer balloon treatment is safe and may provide greater weight loss in higher BMI patients or those desiring a longer weight loss treatment.

Research and development

As of December 31, 2019, we had 7 employees focused on research and development. In addition to our internal team, we retain third-party contractors from time to time to provide us with assistance on specialized projects. We also work closely with experts in the medical community to supplement our internal research and development resources. Research and development expenses for the years ended December 31, 2019 and 2018 were $6.9 million and $10.7 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 numerous clinical trials, which included a total of 1,034 patients as of December 31, 2019. 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.

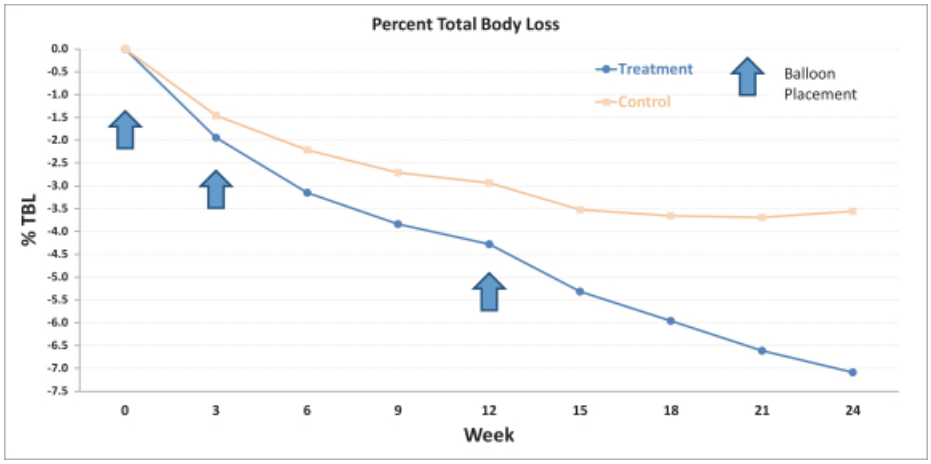
Main Analysis of -5% TBL Responder Rate	Estimate
Obalon Treatment Group—Per Protocol Cohort*	120 / 185 (64.9%)
Sham-Control Group	58 / 181 (32.0%)
Difference (Treatment less Control)	32.8%

* 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.

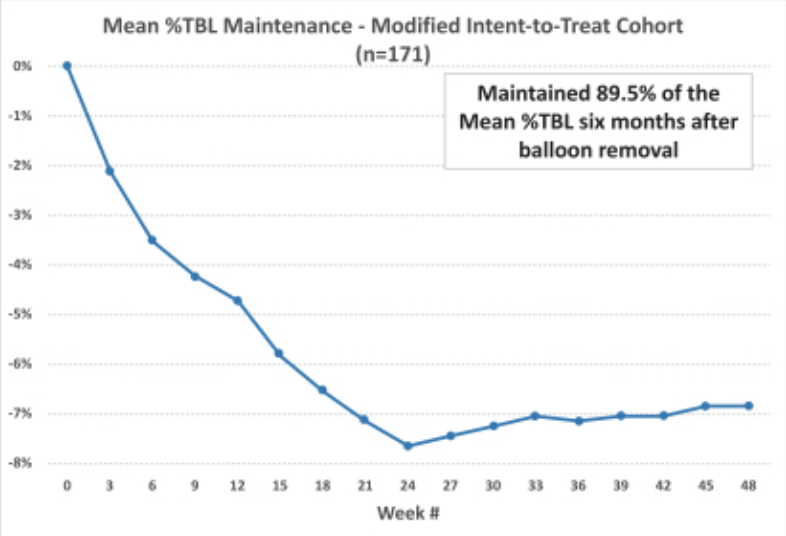


In addition, nearly all patients in the Obalon treatment group, including patients in the bottom 25% of the group, achieved TBL, EWL and weight loss and a reduction in BMI. The table below summarizes the mean, the average of the top 25% of the results, the average of the bottom 25% of the results and 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, 2019, 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 enrolled 187 patients as of December 31, 2019.

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 a minimum of 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.

SALES AND MARKETING

Our primary selling efforts are conducted in the United States, with some sales generated through distributors in select international markets. Historically, we sold our products directly to physicians who would then sell weight loss treatment packages to patients that included our balloon therapy, dietary counseling and balloon removal on a non-reimbursed, self-pay basis. We utilized a direct sales organization consisting of regional sales directors, business development managers, and product specialists. Concurrent with our overall workforce reduction in April 2019, we eliminated our direct sales force in order to transition to our new model of establishing Company-owned or managed Obalon-branded treatment centers rather than focusing our efforts on selling our product directly to physicians.

In the fourth quarter of 2018, we enhanced our capabilities to convert patient interest to treatment by implementing a call center, which we have named an Obalon Ambassador Center, with the capabilities to schedule interested patients to see physicians affiliated with the Obalon Center for Weight Loss™ treatment centers. We believe our Obalon-managed treatment centers will be able to directly leverage these capabilities and allow us to enhance the patient experience, from initial interest through to the completion of patient therapy.

We continue to drive consumer awareness and interest in part through multiple efforts that may include digital, offline and social marketing. We estimate that there were more than 10.5 million views of our digital advertisements and more than 3.5 million views of our digital videos in 2019, compared with 49 million views of our digital advertisements and more than 6 million views of our digital videos in 2018. We also estimate that visits to our website were over 300,000 in 2019 compared to approximately 1.7 million visits in 2018 and searches of our website for physicians capable of placing our Obalon Balloon System were over 43,000 in 2019, compared with 580,000 searches in 2018. We also generated over 20,000 and 71,000 patient leads to our physician partners and the Obalon Center for Weight Loss™ treatment center in the United States during 2019 and 2018, respectively. There were significant changes in spending for digital, offline and social marketing on a quarterly basis throughout 2019 due to the pivot in our commercialization efforts.

The Company-owned or managed Obalon-branded treatment centers employ 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. There are several competitors in the pharmaceutical segment including Vivus, Inc., Eisai Co., Ltd, Inc., AstraZeneca plc, and Allergan plc. 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. 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 has been approved for sale in Europe and the Middle East and completed enrollment in a U.S. clinical trial; and Spatz Medical has also developed a liquid-filled intragastric balloon that has been approved for sale in Latin America and Europe and is currently engaged in a U.S. clinical trial. We also compete against ReShape LifeSciences' Lapband and non-balloon treatments including Aspire Bariatrics' ApireAssist device and 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. BAROnova is developing a non-surgical, non-pharmacologic device to induce weight loss by slowing gastric

emptying. BAROnova completed enrollment of a U.S. clinical trial in January 2017 and submitted a PMA Application in 2018 and gained FDA approval in 2019. 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 plan to continue to 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, 2019, we held 24 issued U.S. patents and had 19 pending U.S. patent applications, as well as 32 international patents issued in regions including Europe, Mexico, Australia, Canada, Asia, China and Israel and 54 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.

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, 2019, we held two registered U.S. trademarks and 41 registered marks throughout Europe, the Middle East, Asia and Mexico. We have five pending U.S. trademark applications and no pending marks outside the United States.

MANUFACTURING

All of our products except the Obalon Navigation System console are 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 with, and we are not contractually obligated to purchase any of our supplies from them. Order quantities and lead times for components purchased from our suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may 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. This risk may be increased as with any new product launch, there is increased risk for supply shortages or product quality issues. 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.

Additionally, we will need to increase our manufacturing capabilities in order to satisfy expected demand for our Obalon Balloon System, and we have no experience manufacturing our Obalon Balloon System in such quantities. If we are unable to keep up with demand for our Obalon Balloon System, our revenue could be impaired, market acceptance for our Obalon Balloon System could be harmed and our customers might instead purchase our competitors' products.

GEOGRAPHIC REGIONS

Substantially all of our assets, revenues and expenses for 2019 and 2018 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. During 2019 and 2018, international revenue accounted for approximately 27.1% 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 plan to have the Obalon balloon CE-mark expire under the previous MDD regulation.

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

Al Danah Medical Company is appointed as our exclusive agent/distributor in Qatar. Qatar recognizes FDA approvals to be sufficient to establish approval within the country. Obalon has obtained U.S. FDA approval for the products and Al Danah obtains the registration that is necessary to permit the purchase and distribution within Qatar. Al Danah sells product directly to hospitals within Qatar.

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 have 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 and expires on May 14, 2020. 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. The Obalon Balloon System is considered a Class 4 (high risk) device when delivered with a porcine-based gelatin capsule. We have appointed Sohail Faris Medical Equipment Trading as the responsible Authorized Representative for the UAE.

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 provide certain services that require the use or disclosure of PHI on behalf of physicians who are covered entities, and we are therefore 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 we do not expect the Obalon Balloon System to be 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.

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 we do not expect the Obalon Balloon System to be covered or reimbursed by any federal healthcare program, we do not believe that our business will be subject to the federal Sunshine Act.

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, 2019, we had 34 full-time employees, and 0 temporary employees. These included 8 in manufacturing and operations, 7 in sales and marketing, 7 in research and development, 7 in clinical affairs, regulatory affairs and quality assurance and 5 in finance, general administrative and executive administration. 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, 2019 and 2018 and our total assets as of December 31, 2019 and 2018, 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 (844) 362-2566. Our website addresses are http://www.obalon.com and http://www.obaloncenter.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 OUR BUSINESS

The report of our independent registered public accounting firm contains an explanatory paragraph indicating substantial doubt about our ability to continue as a going concern.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to invest in (i) the expansion of our Obalon retail treatment center model, (ii) e-centralized customer support for our physician customers, (iii) our marketing programs, (iv) the expansion of our manufacturing facilities and (v) research and development, by conducting clinical trials of our products in development and completing development and commercialization of advancements to our existing Obalon Balloon System. Additionally, we will continue to incur general and administrative costs as a result of supporting growth and operating as a public company. The audit report of our independent registered public accounting firm covering the December 31, 2019 consolidated financial statements contains an explanatory paragraph that states that our recurring losses from operations and liquidity position raises substantial doubt about our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. To date, our operating losses have been funded primarily from outside sources of invested capital and gross profits. We currently need to raise additional cash from outside sources to fund our ongoing operations.

The perception that we may not be able to continue as a going concern may cause third parties including suppliers, customers, and employees to terminate their respective relationships with us due to concerns about our ability to meet our contractual obligations, which could have a material adverse effect on our business.

Execution of our new commercial strategy may not be successful and will subject us to new risks, some of which we may not yet have identified.

Historically we have sold our products directly to physicians, who then sold their patients treatment packages that include our Obalon Balloon System, dietary counseling and removal on a non-reimbursed, self-pay basis. In April 2019, we eliminated approximately 50% of our workforce. As part of the workforce restructuring, we eliminated our field sales force and transitioned to a more centralized customer support model. Going forward, rather than focusing on selling to physicians, we intend to focus our commercialization efforts on establishing and operating Company-owned or managed Obalon-branded retail treatment centers. In September 2019, we opened our first Obalon-branded retail treatment center in California, engaged a medical director, hired non-medical staff to support operations and initiated marketing programs to drive patient interest. Under this model, subject to state law and any federal requirements, we plan to either directly employ the medical personnel or contract for their services, and we will be directly responsible for marketing and patient acquisition. We would also provide the facilities, staff, equipment and support services necessary for patients to receive Obalon balloon therapy. Our intent with this strategic shift is to standardize both quality of care and patient pricing, and provide us greater operational and financial control of our business. While we have historically provided marketing services intended to drive patients to physician offices, we have limited prior experience marketing our products to drive patients to our own centers and we cannot assure you that this new strategic model will be successful.

Our ability to execute this strategy successfully is subject to numerous risks, including:

- difficulty or inability to successfully engage medical personnel to provide medical services for Obalon-owned treatment centers in states that limit the corporate practice of medicine;

- difficulty or inability to successfully recruit and retain qualified physicians, medical personnel and other employees for our Obalon-branded or managed retail treatment centers;
- difficulty or inability to build brand awareness among patients for our products and therapy, or to convert brand awareness and interest into patient visits to our centers;
- difficulty or inability to convince patients of the benefits of treatment with our Obalon Balloon System;
- difficulty or inability in identifying suitable properties for our centers and obtaining leases with acceptable terms;
- timely securing, and for an acceptable cost, all applicable federal, state and local licenses, permits and regulatory approvals;
- timely delivery of leased premises to us from our landlords and punctual commencement and completion of construction;
- the possibility that execution of this strategy will require greater expenditures and investments than we have planned;
- changes in federal, state and local law and regulations that adversely affect our ability to open our centers as well as how we conduct our business;
- changes in economic and other conditions in geographic areas where we open an Obalon-branded retail treatment center that may impact patient demand to receive Obalon balloon therapy;
- unforeseen engineering or environmental problems with leased premises; and
- difficulty or inability to sell the volume of patients necessary for stand alone site profitability.

Additionally, there is no assurance that our current physician customers will be willing to accept the decreased amount of direct field support. Should physicians reject a centralized customer support model, we may experience a negative impact on our results of operations, including a decrease in future sales to existing customers, an increase in our rate of product returns and a decrease in our ability to collect our outstanding accounts receivable. Moreover, without a direct sales force, we expect a very limited amount, if any, of new accounts.

If we are unable to grow our business under our new commercial retail treatment center model, our future revenue and results of operations may be harmed.

We have a relatively short operating history as a commercial company and only recently transitioned to a fundamentally different commercial model focused on the establishment and operation of company owned or managed Obalon-branded retail treatment centers. We have very limited experience in operating Company-owned or managed retail treatment centers and in September 2019 opened our first Company-managed retail treatment center. We will need to develop a retail treatment center management system, and have hired administrative staff, and continue to develop the financial and management controls and information systems to support our Obalon-branded retail treatment center strategy. Attempting to grow our business under this new commercial model imposes significant additional responsibilities on management, including the need to identify, recruit, train and integrate additional employees and the need to design and implement efficient, scalable processes. In addition, potential future growth could place a strain on our administrative personnel, information technology systems, manufacturing operations, and other operational infrastructure. To support any growth, we will need to expand our employee base to increase manufacturing output to meet customer demand while still producing product that meets or exceeds our quality specifications. We have, and may continue to experience difficulties with yields, excess scrap, process design and validation, quality control, component supply and shortages of qualified personnel, among others. Any failure to manage our business cycle in a cost-effective manner could have an adverse effect on our ability to achieve our development and commercialization goals, which in turn could adversely impact our business and results of operations.

We expect to need additional financing in order to support our operating plan.

We recently initiated the transition of our commercialization efforts to focus on Obalon-branded or managed retail treatment centers. We have opened two such facilities and expect that we will need additional capital to continue to execute on this strategy. However, adequate funding may not be available to us on acceptable terms, or at all. The failure to obtain sufficient funds on acceptable terms or in a timely manner could force us to take actions that could materially and adversely affect our business. We also cannot give assurance that we will achieve sufficient revenues in the future to achieve profitability and cash flow positive operations to allow us to continue as a going concern.

Our future capital requirements will depend on many factors, including:

- the degree of success we experience in commercializing our Obalon Balloon System with both Obalon-branded or managed retail treatment centers and centralized customer support model;
- the rate at which the currently small and immature intragastric balloon market develops;
- our ability to scale manufacturing in a cost-effective manner to meet demand;
- costs associated with opening and operating Company-owned or managed Obalon-branded retail treatment centers;
- operational expenses associated with Obalon-branded or managed retail treatment centers, the cost and expense of our marketing infrastructure, and our manufacturing operations;
- the revenue and gross profit generated by sales of our Obalon Balloon System, Obalon Navigation System, and any other products that may be approved in the United States;

- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our products under development;
- the costs and timing of establishing and expanding the Obalon-branded or managed retail treatment centers;
- the costs and timing of developing enhancements of our Obalon Balloon System and Obalon Navigation System and obtaining FDA clearance or approval of such enhancements;
- the emergence of competing or complementary technological developments;
- the extent to which our Obalon Balloon System and Obalon Navigation System are adopted by the physician community and patients;
- the number and types of future generation products we develop and commercialize and their success and adoption in the marketplace;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- costs of operating as a public company and compliance with existing and future regulations;
- the extent and scope of our general and administrative expenses;
- the legal costs associated with defending against shareholder litigation; and
- the degree of success we experience in international sales of our Obalon Balloon System.

We may raise funds in equity or debt financings, including pursuant to our purchase agreement with Lincoln Park Capital, or enter into additional credit facilities in order to access funds for our capital needs. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our lack of sufficient funds could cause us to terminate or delay the development of the Company-owned or managed Obalon-branded retail treatment centers, negatively impact services associated with our centralized customer support model, delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay other activities necessary to commercialize our products. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

We have 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 commencing after the satisfaction of certain conditions, including that the SEC has declared effective the registration statement related to the shares. 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. As of December 31, 2019, we have sold 356,122 shares to Lincoln Park under a prior financing arrangement with Lincoln Park Capital for up to $20 million that was executed in December 2018. 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 Global 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. Our 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 our business.

We have limited operating experience and a history of net losses, and we may not be able to achieve or sustain profitability.

We have a limited operating history and have focused primarily on commercial execution, research and development, clinical trials, product engineering and building our manufacturing capabilities. Before launching our prior generation Obalon Balloon System in the United States in January 2017, we sold an earlier generation of our product in certain international markets. Our commercial sales experience has been limited. We have incurred significant losses in each period since our inception in 2008, with net losses of $23.7 million and $37.4 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of approximately $172.4 million and had cash and cash equivalents of $14.1 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, sell our Obalon Balloon System in international markets, and commercialize our Obalon Balloon System in the United States. Our consolidated financial statements as of and for the year ended December 31, 2019

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. Based on our cash balances and recurring losses since inception, there is substantial doubt about our ability to continue as a going concern and if we are not able to raise additional capital in a timely manner, we will not be able to support our ongoing operations.

We expect our costs and expenses to increase in the future as we continue U.S. commercialization of our product, including the cost associated with the Obalon-branded or managed retail treatment centers, our new centralized customer support model, investment to develop the immature intragastric balloon market, and the expansion of our manufacturing capacity. In the centralized customer support model, we sell the Obalon Navigation System console to physicians at a price that approximates our cost and will negatively impact future gross profit dollars and gross margin percentage. We have limited experience manufacturing the Obalon Navigation Balloon, and as a result expect lower gross profits. We will also continue to invest in research and development of new product candidates, including conducting clinical trials of our products currently in development. In addition, as a public company, we incur significant insurance, legal, accounting, compliance and other expenses that we would not incur as a private company. As a result, we expect our losses to continue for the foreseeable future. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

We are currently a single product company with limited commercial sales experience, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

We were incorporated in 2008, and prior to January 2017 our business activities were focused on the development and regulatory approval of our Obalon Balloon System and building the commercial infrastructure to sell our product in the United States. We commenced commercial launch of our prior generation Obalon balloon system in the United States in January 2017 and commenced commercial shipments of our most recent iteration of our Obalon Balloon System, Obalon Navigation System and Obalon Touch Inflation Dispenser in the United States in the first quarter of 2019. In 2019, we fundamentally changed our commercialization efforts by eliminating our field sales force and commencing operation of the first Company-managed retail treatment center. All of our revenue prior to initial operations of the retail treatment center was attributable to sales of our Obalon Balloon System including its component parts and accessories. In the future, while we expect to continue to generate some sales of our products to physicians through a centralized customer support model, we anticipate deriving the majority of our U.S. revenue from our Company-owned or managed Obalon-branded retail treatment center model. Through 2016, our primary commercial sales experience was limited to sales to distributors in a limited number of countries outside the United States. Our limited operating and commercialization experience in what we expect will be our primary market and our reliance on a new retail commercialization strategy make it difficult to evaluate our current business and predict our future prospects. Throughout 2019, we began phasing out our prior generation Obalon balloon system that uses x-ray technology to place balloons and intend to only sell versions of the Obalon Balloon System that use the Obalon Navigation System to place balloons. In the centralized customer support model for physicians, use of the Obalon Navigation System requires the physician to make a capital purchase of the Navigation console and Obalon Touch Dispenser.. We cannot assure you that our current physician customers will be willing to make that purchase, and if we cannot transition physicians who currently use the prior generation Obalon balloon system to the Obalon Navigation System, we may experience a further decline in physician generated sales. A number of factors that are outside our control may contribute to fluctuations in our financial results, including:

- patient demand for our Obalon Balloon System, including the rate at which patients seek treatment from physicians, at our Company-owned or managed Obalon-branded retail treatment centers or otherwise;
- the degree of success we experience in commercializing our Obalon Balloon System with both the Company-owned or managed Obalon-branded retail treatment centers and centralized customer support model;
- 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 three Letters to Health Care Providers warning them about the use of liquid-filled intragastric balloons citing potential risks, including death;
- our ability to develop, finance, obtain regulatory approval for, and successfully launch our next generation products and the success of our next generation products in the marketplace;

- our ability to develop, obtain regulatory approval for, and successfully manage the Company-owned or managed Obalon-branded retail treatment center;
- our ability to service and maintain equipment such as the Obalon Navigation System;
- our ability to maintain our current or obtain further regulatory clearances, licenses or approvals;
- 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;
- performance of our international distributor; 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 are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.

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 carry a high level of inventory for strategic materials and products and are subject to the risk of inventory obsolescence. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. In addition, because we are a vertically integrated manufacturer, insufficient demand for our products may subject us to the risk of high inventory carrying costs and increased inventory obsolescence.

Opening Obalon-branded retail treatment centers in existing markets where we have historically sold direct to physicians may negatively affect revenue with our current physician customers.

The target area of our centers varies by location and depends on a number of factors, including population density, other available retail and medical services, area demographics and geography. As a result, the opening of an Obalon-branded retail treatment center in or near markets in which we already have physician customers could adversely affect the revenues of those existing physician customers. Existing physician customers could also make it more difficult to build our patient base for a center in the same market. Our business strategy does not entail opening Obalon-branded retail treatment centers that we believe will materially affect revenue at our existing physician customers, but we may selectively open centers in and around areas of existing physicians customers to effectively serve our patients. Revenue “cannibalization” between our centers and physician customers may become significant in the future as we continue to expand our operations and could affect our revenue growth, which could, in turn, adversely affect our business, financial condition and results of operations.

We will be subject to all of the risks associated with leasing space subject to long-term non-cancelable leases for Obalon-branded retail treatment centers that we intend to operate.

We do not own and we do not intend to own any of the real property where our Company-owned or managed centers will operate. We expect to lease the spaces for the Company-owned or managed centers we intend to open in the future. We may not be able to locate appropriate properties and obtain leases in a timely manner, on favorable terms or at all. If a future Company-owned or managed center is not profitable, resulting in its closure, we may nonetheless be committed to perform our obligations under the applicable lease including, among other things, paying the base rent for the balance of the lease term. In addition, we may fail to negotiate renewals as each of our leases expires, either on commercially acceptable terms or at all, which could cause us to pay increased occupancy costs or to close centers in desirable locations. These potential increases in occupancy costs and the cost of closing Company-owned or managed centers could materially adversely affect our business, financial condition or results of operations.

Patients may be 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. If any of these events were to occur, our business and prospects would be negatively affected.

Intragastric balloons represent a relatively new category of treatment for obese and overweight patients that is small and immature. Currently, we are aware of only one other intragastric balloon available for sale in the United States, which was first commercially available in 2015. As a result, patient awareness of intragastric balloons as a treatment option for obesity and weight management, and experience with intragastric balloons, is minimal. To date, we have experienced limited penetration of this market, and our success depends in large part on our ability to further develop the currently small and immature intragastric balloon market, educate patients, and successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our Obalon Balloon System. In April 2019, as part of a restructuring, we eliminated our direct field sales force and transitioned to a centralized customer support model for our existing physician customers and focused our efforts on establishing our first company-managed Obalon-branded retail treatment center. We expect to continue investing in the various activities to develop the intragastric balloon market for the foreseeable future. Since we received PMA approval for the Obalon Balloon System in September 2016, we have launched various marketing campaigns to raise awareness of our Obalon Balloon System and its benefits among patients and physicians, but we cannot assure you that these efforts will be successful or that they will not prove to be cost-prohibitive.

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 three 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 and 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.

If we fail to grow our sales and marketing capabilities and develop widespread brand awareness cost effectively, our financial performance and business may suffer.

We have limited experience as a company in the sales and marketing of our products. 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 commenced commercial shipments of our Obalon Navigation System in the first quarter of 2019. In the fourth quarter of 2019, we opened our first Company-managed retail treatment center. We anticipate the United States and our Company-owned or managed Obalon-branded retail treatment center model to be our primary market focus going forward. We recently eliminated our direct sales force and now sell to physicians through a centralized customer support model. In the centralized customer support model, marketing and clinical support is provided from our corporate office. Marketing support may include media assets and leads generated from our Find-A-Doc locater. Training our applicable employees in use of our Obalon Balloon System and Obalon Navigation System to achieve the level of clinical competency expected by physicians, and to comply with applicable federal and state laws and regulations and our policies and procedures requires significant time, expense and attention. Our business may be harmed if there is excessive turnover in our employees or our efforts to train and retain our employees do not generate a corresponding increase in revenues. If we are unable to hire, develop and retain talented personnel or if new personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenues sufficiently to offset the cost incurred.

In addition, factors that may inhibit our efforts to commercialize our Obalon Balloon System, Obalon Navigation System and any other products that may receive FDA approval include:

- the inability of our employees to perform their duties and conduct business in a manner that is compliant with our internal policies and procedures and FDA law and regulations;
- unforeseen costs and expenses associated with our centralized customer support model, including the marketing organization;
- efforts by our competitors to commercialize products or procedures that address a similar patient population; and
- the existence of negative publicity about us or our products.

Our ability to develop broader market acceptance of our Obalon Balloon System will depend to a significant extent on our ability to efficiently expand our marketing programs which create patient and physician demand for our product. We have in the past and plan to in the future, dedicate significant financial and other resources to our marketing programs. Our investments in marketing have varied over time and were significantly reduced as we transitioned to our new business strategies of centralized customer support for our physician customers and the Obalon-branded retail treatment centers. In September 2019, we reinitiated marketing programs to increase patient interest for the Obalon Center for Weight Loss™ treatment center. Our business will be harmed if our marketing efforts and expenditures do not generate a sufficient increase in revenue to offset their cost.

In addition, we believe that developing and maintaining awareness of our brand in a cost-effective manner is critical to achieving acceptance of our product and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract the patients necessary to realize a sufficient return on our brand-building efforts, or to achieve brand awareness that is critical for broad patient adoption of our Obalon Balloon System.

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.

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.

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 is inflated in another portion of the body, such as 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.

We actively 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 do not expect that patients will receive third-party reimbursement for treatment using our products. As a result, we expect that our success will depend on the ability and willingness of patients to pay out-of-pocket for treatment with our products.

Certain elective treatments, such as an intragastric balloon, are typically not covered by insurance. Accordingly, we do not expect that any third-party payers will cover or reimburse physicians or patients for the Obalon Balloon System. As a result, our success will also depend on the ability and willingness of patients to pay out-of-pocket for treatment with our products.

Our Company-owned or managed Obalon-branded retail treatment centers need to achieve a certain level of new patient treatments to be successful. Adverse changes in the economy may cause consumers to reassess their spending choices and reduce the demand for elective treatments and could have an adverse effect on consumer spending. This shift could have an adverse effect on our net sales. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products. The decision by a patient to elect to undergo treatment with the Obalon Balloon System may be influenced by a number of additional factors, such as:

- the success of any sales and marketing programs, including direct-to-consumer marketing efforts, that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which the Obalon Balloon System satisfies patient expectations;
- the general perception of the Obalon Balloon System in the consumer market;

- the cost, safety, comfort, tolerability, ease of use, and effectiveness of the Obalon Balloon System as compared to other treatments; and
- general consumer confidence, which may be impacted by economic and political conditions.

Our financial performance will be materially harmed if we cannot generate significant patient demand for the Obalon Balloon System.

We do not expect revenue associated with sales to physician customers to represent a significant portion of our revenue for the foreseeable future.

We are currently focused on developing and growing our retail treatment center model and, as a result, we no longer directly market our products to physicians. While we continue to sell our products to physicians upon their request, unless and until we resume direct marketing activities aimed at physicians, we do not expect revenue associated with physician sales to be significant.

Physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our Obalon Balloon System for recommendation to patients for a variety of reasons, including:

- lack of access or reluctance to acquire access to ancillary equipment such as endoscopy which is necessary to remove the Obalon Balloon System;
- reluctance to invest in ancillary equipment, such as the Obalon Navigation System, which is necessary to place an Obalon balloon;
- inability to develop the appropriate practice management programs, which include treatment protocols, nutritional counseling and patient management, to treat patients in a manner consistent with our treatment protocol;
- long-standing relationships with competitors and distributors that sell other products and their competitive response and negative selling efforts;
- lack of reimbursement for physicians providing treatment with our products;
- lack of experience with our products and concerns that we are relatively new to the obesity market, or concerns that our competitors offer greater support or have larger amounts of resources than our company;
- lack of confidence in Obalon continuation of operations or ability to effectively shift to a centralized support model;
- perceived liability risk generally associated with the use of new products and procedures;
- lack or perceived lack of sufficient clinical evidence supporting clinical benefits;
- reluctance to change to or use new products;
- perceptions that our products are unproven or experimental;
- time and skill commitment that may be required to gain familiarity with a new system; and
- difficulty convincing physicians of the economic benefit of our product to their practice.

If physicians are unable or unwilling to make the necessary financial and regulatory commitments and implement the appropriate practice management programs to successfully treat patients with the Obalon balloon, they may not adopt our balloon system.

Moreover, there is a learning process involved for physicians to become proficient in the use of our products. In addition, it is also critical for physicians to be educated and trained on best practices in order to achieve optimal results, including patient selection and eligibility criteria as well as complementary methods of use such as diet or behavioral modification programs. Convincing physicians to dedicate the time and resources necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. This training process may also take longer than we expect. If physicians are not properly trained in the use of our Obalon Balloon System, they may misuse or ineffectively use our products for the treatment of patients. As a result, patients have experienced adverse events and have not been able to enjoy the benefits of our system or achieve the weight loss outcomes they expected, leading to dissatisfaction and could lead to market rejection of our products. A physician's failure to follow our instructions for use or other misuse of our products in any stage of the treatment can result in, among other things, patient injury, adverse side effects, negative publicity or lawsuits against us. Any of these events could have an adverse effect on our business and reputation.

We have limited experience manufacturing our Obalon Balloon System and Obalon Navigation System in commercial quantities and 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, and we will need to adjust our manufacturing capabilities in order to satisfy expected demand. We may find that we are unable to successfully manufacture these new products in sufficient quantities and expect manufacturing of the Obalon Navigation Balloon to be at a much higher per unit cost initially. We may need to adjust our manufacturing capabilities in order to satisfy expected demand for our Obalon Navigation balloon. In addition, the Obalon Navigation balloon with the Obalon Touch Inflation Dispenser utilizes a different catheter and dispenser configuration from our prior U.S. product, which we have limited experience manufacturing in commercial quantities.

Furthermore, in June 2019 we initiated a facility reduction plan that included consolidating certain functions of manufacturing. There were certain quality system requirements we needed to satisfy in order to restart our manufacturing operations. The quality system requirements were satisfied in July 2019 and manufacturing operations resumed.

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

- the reduction in workforce in April 2019 could negatively impact our ability to meet an increase in demand;
- 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;
- 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.

As we have scaled manufacturing, we have experienced challenges in our ability to meet fluctuating commercial demand. While we have taken steps to address these challenges, we cannot assure you those steps will be sufficient or that additional challenges will not arise as we continue with the commercialization of our Obalon Balloon System and the recently commercialized Obalon Navigation System. If we continue to experience these challenges, our revenue could be impaired, our costs could increase, market acceptance for our product could be harmed and our customers might instead purchase our competitors' products. Our inability to successfully manufacture components of our Obalon Balloon System in quantities sufficient to meet expected demand would materially harm our business.

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 currently manufacture our Obalon Balloon System and some of its components and sub-assemblies at our Carlsbad facility and we rely on third-party suppliers for other components and sub-assemblies used in production. In some cases, these suppliers are single source suppliers. For example, we rely 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 rely 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. Any 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 Obalon and result in delayed or canceled delivery of components, which could result in production challenges. Suppliers could also modify payment terms, including upfront cash payments. 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 production and 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;
- 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.

International sales represented 27.1% and 48.4% of our total revenue for the years ended December 31, 2019 and 2018, 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. In the first quarter of 2019, we completed final shipments of the prior generation product to Bader. The agreement with Bader was terminated in December 2019. In December 2019, we entered into a one-year distribution agreement with Al Danah Medical Company W.L.L., a distributor in Qatar. In the first quarter of 2019, we initiated shipments of the Obalon Balloon System to Al Danah. The significant reduction in international revenue in 2019 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.

We do not currently 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. There are several competitors in the pharmaceutical segment including Vivus, Inc., Eisai Co., Ltd, Inc., AstraZeneca plc, and Allergan plc. 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 balloon that has been approved for sale in Europe and the Middle East and completed enrollment in a U.S. clinical trial and is pending FDA approval. Spatz Medical has also developed a liquid-filled intragastric balloon that has been approved for sale in Latin America and Europe and is currently engaged in a U.S. clinical trial. We also compete against non-balloon treatments including Aspire Bariatrics' ApireAssist device and 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. Gelesis's Plenity device was cleared by FDA in 2019. Also in 2019, BAROnova gained FDA PMA approval in the U.S. for its transpyloric shuttle, a non-surgical, non-pharmacologic device to induce weight loss by slowing gastric emptying. 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.

If our manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to manufacture and sell our Obalon Balloon System and to pursue our research and development efforts may be jeopardized.

We manufacture and assemble our Obalon Balloon System in our single manufacturing facility in Carlsbad, California. Our products consist of components sourced from a variety of contract manufacturers and suppliers, with final assembly completed at our facility. In early 2019 we began commercial manufacturing of our current generation Obalon Balloon System and all of its related components. We have limited experience manufacturing these products, which could result in supply shortages or interruptions. The Obalon Navigation System console is entirely manufactured by a single source supplier and shipped to our single manufacturing facility in Carlsbad, California. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, hurricane, terrorism, flooding and power outages. Any of these may render it difficult or impossible for us to manufacture products for an extended period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products, particularly as the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems would require FDA review and approval of a PMA supplement. In June 2019 we initiated a facility reduction plan which included consolidating certain functions of manufacturing. There were certain quality system requirements we needed to satisfy in order to restart our manufacturing operations. The quality system requirements were satisfied in July 2019 and manufacturing operations resumed.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Although we have entered into employment agreements with some of our executive officers and key employees, each of them may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. In the second quarter of 2019, Kelly Huang resigned from his role as President and Chief Executive Officer and William Plovanic, the Chief Financial Officer at the time, was appointed to fill the role of President. In the fourth quarter of 2019 we promoted William Plovanic to Chief Executive Officer from his prior role of Chief Financial Officer and he has continued to serve as President. In the fourth quarter of 2019, we also promoted Nooshin Hussainy to Chief Financial Officer from her prior role of Vice President

Finance and Controller. Andrew Rasdal continues to serve as Executive Chair of the Board of Directors, the role to which he was appointed in January of 2019.

We do not currently maintain key personnel life insurance policies on any of our employees.

To execute our business and growth plan, we must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales and marketing personnel with experience selling and marketing directly to patients and physicians and/or institutions. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

In April 2019, we announced an organizational restructuring, which eliminated our direct field sales force and reduced our headquarters staff, which included the loss of our Vice President of Quality Assurance, and in June 2019, our Vice President of Research and Development accepted a voluntary separation package. In August 2019, our Vice President of Marketing accepted a voluntary separation package and we accepted the resignation of our Vice President of Operations. Our Chief Retail Officer assumed the responsibilities for the Vice President of Marketing, our Chief Quality Assurance, Clinical & Regulatory Affairs Officer assumed the responsibilities for the Vice President of Quality Assurance, and our Chief Technology Officer assumed responsibilities for the Vice President of Operations. Replacing these individuals, and other executive officers and key employees that may depart, has been difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize medical devices. Retention of key employees may be impacted by the recent decreases in our stock price, which results in smaller current values of employee retention grants.

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.

Changes in coverage and reimbursement for obesity treatments and procedures could affect the adoption of our Obalon Balloon System and our future revenues.

Currently, intragastric balloon products are not generally covered or reimbursed by third-party payors. We do not plan on submitting any requests to any third-party payor for coverage or billing codes specific to our products. However, payors may 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. For example, healthcare reform legislation or regulation that may be proposed or enacted in the future that results in a favorable change in coverage and reimbursement for competitive products and procedures in weight loss and obesity could also negatively impact adoption of our products and our future revenues, and our business could be harmed as we would be at an economic disadvantage when competing for customers.

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.

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.

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.

Our Company-owned or managed Obalon-branded retail treatment centers may subject us to professional liability claims if one or more of our affiliated physicians causes harm to patients, and we may be unable to obtain or maintain adequate insurance against these claims.

We have established two Company-managed Obalon-branded retail treatment centers and intend to establish additional Company-owned or managed Obalon-branded retail treatment centers, where medical services will be provided to the public, which will expose us to the risk of professional liability and other claims. In recent years, physicians have become subject to an increasing number of lawsuits alleging malpractice and related legal claims. Some of these lawsuits may involve large claims and significant defense costs. It is possible that these claims could be asserted against us and/or our affiliated physicians. Any litigation, if successful, could result in substantial damage awards to the claimants that may exceed the limits of any applicable insurance coverage. Although we will not be making patient care or treatment decisions at the Company-owned or managed Obalon-branded retail treatment centers, it could be asserted that we should be held liable for the malpractice of a physician using our products at a Company-owned or managed Obalon-branded retail treatment center. In addition, we could incur reputational harm or negative publicity in relation to a material malpractice or care-related injury. Malpractice lawsuits and claims can also lead to increased scrutiny by regulatory authorities and other third parties. Some plaintiffs have asserted allegations of corporate practice of medicine or prohibited fee splitting in connection with malpractice claims. There can be no assurance that a future claim or claims will not be successful or, if successful, will not exceed the limits of available insurance coverage. Professional liability insurance, moreover, can be expensive and varies from state to state and there can be no assurance that professional liability insurance will be available to us or our affiliated physicians at costs acceptable to us or at all.

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 three 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.

Our international operations subject us to regulatory and legal risks and certain operating risks, which could adversely impact our business, results of operations and financial condition.

The sale of our Obalon Balloon System across international borders and our international operations subject us to U.S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance.

Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws and economic sanctions laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant costs and disruption of business associated with an internal and/or government investigation, criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- foreign currency exchange rate fluctuations;
- a shortage of high-quality sales people and distributors;
- pricing pressure that we may experience internationally;
- competitive disadvantage to competitors who have more established business and customer relationships;
- reduced or varied intellectual property rights available in some countries;
- economic instability of certain countries;
- the imposition of additional U.S. and foreign governmental controls, regulations and laws;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us; and
- laws and business practices favoring local companies.

If we experience any of these events, our business, results of operations and financial condition may be materially harmed.

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. 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 or 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. 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.

Our results of operations could be negatively impacted if we are unable to collect our accounts receivable or if we experience a large number of product returns.

We reserve for sales returns as a reduction to revenue based on our historical experience with return rates and the specific circumstances which lead us to believe a customer may return product. If we experience a large number of product returns or an unexpected increase to product return rates, it would have a negative impact on our revenue and results of operations.

In our Company-managed Obalon-branded retail treatment centers payment is collected from the patient in advance of initiation of treatment and payments will be handled the same way for any future Company-owned or managed Obalon-branded treatment centers. Third party financing is offered at the Obalon Center for Weight Loss™ by companies that specialize in that service. If patients are not satisfied with the outcome of the treatment, or experience complications or early removals, they may request refunds. We reserve for sales returns as a reduction of revenue. If we experience a higher than expected request for refunds, it could have a negative impact on our revenue or results of operations.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.

Clinical development of Class III medical device systems and accessories such as the Obalon Balloon System is a rigorous, lengthy, expensive and uncertain process. It is also subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical data will be found reliable by

the FDA, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities and support product approval. Successful results of pre-clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, the FDA or foreign regulatory authorities may disagree with our analyses and interpretation of the data from our clinical trial, or may find the clinical trial design, conduct, monitoring, or results unreliable or inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of our products. The data we collect from our clinical trials may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance or approval to market our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the obtainment of the right to affix the Certificat de Conformité, or CE, mark in the European Union, the submission to the FDA of an IDE application, PMA application, or PMA supplement, the enrollment of patients in clinical trials, the release of data from clinical trials, and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Clinical trials are necessary to support PMA applications for our device and may be necessary to support PMA supplements for modified versions of our marketed device products or to support comparative safety, effectiveness or performance claims. This could require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial.

We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, for new or expanded indications for use for existing products, or for comparative safety, effectiveness, or performance claims for existing products, including new indications for existing products, including:

- enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory, and there may be side effects from device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- we may have trouble in managing multiple clinical sites or adding a sufficient number of clinical trial sites;
- we may have trouble addressing any patient safety concerns that arise during the course of a clinical trial;
- we may experience delays in agreeing on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; and
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the trial patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient

compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or suffer adverse medical events or death whether related or not to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delay, or result in the failure of the clinical trial.

We could also encounter delays if the FDA or foreign regulatory authority concluded that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or the FDA or foreign regulatory authority concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of our application by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

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.

We may acquire other companies or technologies, which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our results of operations.

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our Obalon Balloon System, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth in our business has been organic, and we have no experience in acquiring other businesses. In any acquisition, we may not be able to realize the benefits of acquiring such businesses if we are unable to successfully integrate the acquired business with our existing operations, technologies and company culture. We cannot assure you that following any such acquisition we would achieve the expected synergies to justify the transaction.

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, 2019, we had federal and state net operating loss carryforwards, or NOLs, of approximately $147.9 million and $114.6 million, respectively. The federal and state tax loss carryforwards will begin expiring in 2028, unless previously utilized. The federal net operating loss carryover includes $59.7 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.

RISKS RELATED TO REGULATORY MATTERS

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 December 31, 2019 we enrolled 187 patients. 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. 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 three 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. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FFDCA. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. These proposals

have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could increase the costs of compliance, or otherwise create competition that may negatively affect our business. 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.

In the United States, before we can market a new medical device, or label and market a previously cleared or approved device for a new intended use or new indication for use, or make a significant modification to a previously cleared or approved device, we must first receive either FDA clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or approval of a PMA application from the FDA, unless an exemption applies. The process of obtaining PMA approval, which was required for the Obalon Balloon System, is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, in order to clear the proposed device for marketing. 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. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk.

Modifications to products that are approved through a PMA application generally need FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to twelve months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals would have a material adverse effect on our business, financial condition and prospects.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;
- the applicable regulatory authority may identify deficiencies in the chemistry, manufacturing and control sections of our application, our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers;
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- the FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support a PMA application.

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, 2019 we enrolled 187 patients. 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. 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. 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 products to be reviewed and/or cleared 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA 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 Ballloon System will not be renewed in May 2020. 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 our 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 our operation of retail treatment centers, arrangements with physicians and interactions with retail customers in the near future 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 the 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 are required to be HIPAA compliant and have created the policies, procedures and completed training as required. 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.

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, our research and development and manufacturing 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 the resultant waste materials are disposed of 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, 2019, we held 24 issued U.S. patents and had 19 pending U.S. patent applications, as well as 32 international patents issued in regions including Europe, Mexico, Australia, Canada, Asia, China and Israel and 54 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, 2019, we held two registered U.S. trademarks and 41 registered marks in Europe, the Middle East, Asia and Mexico. We have five pending U.S. trademark applications and no pending marks outside the United States, including in Europe, the Middle East, Asia and Mexico.

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; or
- that our commercial activities or products will not infringe the patents of others.

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.

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 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 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 an 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.

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;
- successful execution of our new commercial strategy;
- 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 Global 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 May 15, 2019, we received a written notification from Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450(b)(1)(A) based on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, which reported our stockholders' equity as $6,518,000, which is below the minimum of $10,000,000 in stockholders' equity required for continued listing. On May 16, 2019, we received a second written notification from Nasdaq notifying us that the closing bid price for our common stock had been below $1.00 for the last 30 consecutive business days and that we were not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). We were able to regain compliance with both of these listing requirements prior to Nasdaq actually delisting our common stock; however, there can be no assurance that we will maintain compliance with these or any other Nasdaq listing rules, in which case Nasdaq could determine to delist our common stock.

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. If one or more of the analysts who cover us 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 one or more of the remaining analysts cease coverage of our company or fails 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.

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.

In addition, sales of a substantial number of shares of our outstanding common stock in the public market could occur at any time. Persons who were our stockholders prior to our initial public offering, or IPO continue to hold a substantial number of our common stock that many of them are now able to sell in the public market. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of shares of our common stock are also entitled to rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also intend to register shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they can be sold freely in the public market upon issuance, subject to volume limitations applicable to affiliates.

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.

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

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

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.

We will continue to incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives.

As a public company, and particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq, have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside

consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

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

We also expect that being a public company and compliance with applicable rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantially higher costs to obtain and maintain the same or similar coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors.

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, 2019, 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. We believe the remaining claims in the complaint are without merit and intend to defend vigorously against them.

On December 12, 2019, a purported stockholder submitted a formal demand letter to the Board asserting similar alleged wrongdoing as alleged in the securities class action and demanding that the Board investigate the alleged wrongdoing and take action to remedy the alleged injury to the Company. The Board's review of the demand is on-going.

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.

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.

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.

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.

As of February 27, 2020, we have entered into 3 leases for Obalon-branded retail treatment centers in California, encompassing an aggregate of approximately 6,725 square feet with terms expiring between 2021 and 2025.

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. We believe the remaining claims in the complaint are without merit and intend to defend vigorously against them.

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 trades under the symbol “OBLN.” Prior to October 6, 2016, there was no public market for our common stock.

Holders of Record

As of February 18, 2020, there were approximately 38 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 2020 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, 2019, 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, 2019 and 2018 and the selected consolidated balance sheet data as of December 31, 2019 and 2018 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, 2017 and 2016 and the selected consolidated balance sheet data as of December 31, 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,			
	2019	2018	2017	2016
Consolidated statements of operations data:				
Revenue:				
Revenue	$ 3,281	$ 9,101	$ 9,914	—
Revenue, related party	—	—	—	3,393
Total revenue	3,281	9,101	9,914	3,393
Cost of revenue	2,950	5,423	4,829	2,809
Gross profit	331	3,678	5,085	584
Operating expenses:				
Research and development	6,893	10,697	10,647	9,872
Selling, general and administrative	16,668	29,946	28,829	10,217
Total operating expenses	23,561	40,643	39,476	20,089
Loss from operations	(23,230)	(36,965)	(34,391)	(19,505)
Interest expense, net	(385)	(226)	(135)	(477)
Loss from change in fair value of warrant liability	—	—	—	(466)
Other expense, net	(61)	(189)	(239)	(19)
Net loss	(23,676)	(37,380)	(34,765)	(20,467)
Other comprehensive income (loss)	—	5	(4)	(1)
Net loss and comprehensive loss	$ (23,676)	$ (37,375)	$ (34,769)	$ (20,468)
Net loss per share, basic and diluted[1]	$ (5.03)	$ (19.64)	$ (20.80)	$ (48.47)
Weighted-average common shares outstanding, basic and diluted[1]	4,706,775	1,903,734	1,671,796	422,324

(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,			
	2019	2018	2017	2016
Consolidated balance sheet data:				
Cash and cash equivalents and short-term investments	$ 14,055	$ 23,735	$ 44,400	$ 75,475
Working capital	14,258	11,416	41,744	73,469
Total assets	20,393	30,386	53,101	78,778
Term loan	—	9,930	9,922	9,881
Accumulated deficit	(172,430)	(148,754)	(111,374)	(76,609)
Total stockholders' equity (deficit)	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: a favorable safety profile, improved patient tolerability and comfort, progressive weight loss with durable results, simple and convenient placement, and potentially attractive economics for patients.

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, reversible and repeatable weight loss solution in an outpatient setting, without altering patient anatomy or requiring surgery.

The current generation of our 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; 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. 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 progressive weight loss with durable results. In addition, data presented from our commercial registry demonstrates greater weight loss in the commercial setting as compared to clinical studies. In our 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 addition, patients in the Obalon treatment group showed, on average, progressive weight loss over the entire six-month balloon treatment period, and maintained, on average, 89.5% of the weight loss six months after balloon removal.

In December 2018, data from our commercial registry was analyzed on more than 1,300 patients at 108 treatment sites. For those patients who received three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in 9.9% reduction in total body weight and a 3.5 point decrease in BMI compared to baseline values. Of note, the top quartile of those patients lost an average of 39 pounds, resulting in a 16.8% reduction in total body weight and a 6.2 point decrease in BMI compared to baseline values. Furthermore, in May 2019, analysis of data from our commercial registry was updated to include 1,411 total patients from 143 treatment sites in the United States. In this larger 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. Weight loss in the first months of therapy was the largest predictor of success.

We commenced U.S. commercialization of our prior generation Obalon balloon system in January 2017. In February 2019, we commercialized our current generation Obalon Balloon System with the Obalon Touch Inflation Dispenser and our Obalon Navigation System, which together are designed to make balloon placement more reliable, safer, easier and less expensive. The Obalon Navigation System is designed to eliminate the need to use x-ray technology when placing the Obalon balloon.

When we commenced commercial operations, we relied on a direct sales force to sell our products directly to physicians, who would then sell weight loss treatment packages to their patients that included our balloon therapy, dietary counseling and balloon removal on a non-reimbursed, self-pay basis. In 2019, we began implementing a fundamental change to our commercialization efforts, pursuant to

which we would establish Company-owned or managed Obalon-branded retail treatments centers. The transition commenced with the elimination of our direct sales force in connection with an overall workforce reduction in April 2019. Concurrent with that reduction, we transitioned to a centralized customer support model through which we sell to existing physician customers or new physicians that contact us directly to acquire the Obalon Balloon System and provide marketing and clinical support to those physicians. Marketing support may include media assets and leads generated from our Find-A-Doc locator and leads generated from our digital and off-line marketing efforts.

In September 2019, the first Company-managed Obalon Center for Weight Loss™, opened, in San Diego, California. In February 2020, a second Obalon-managed Obalon Center for Weight Loss opened in Orange County, California. At these Company-managed retail treatment centers, patients can be prescribed and received treatment with the Obalon Balloon System. Each treatment center is wholly-owned by a physician through a separate professional entity. As manager of the facility, we provide the office support, non-clinical staff, equipment, marketing support, and other administrative services to the center where patients receive the Obalon balloon therapy from licensed physicians. We intend to manage additional Obalon Centers for Weight Loss and, where permissible under state law, to open Company-owned treatment centers, where we would directly employ or contract with physicians and other healthcare professionals who prescribe and administer the treatments. We believe this model will contribute to standardization of both quality of care and patient pricing, and provide us greater operational and financial control of our business.

We intend to continue to drive patient awareness and interest in part through multiple efforts that may vary over time and may include digital, offline and social marketing. We estimate that there were more than 10.5 million views of our digital advertisements and more than 3.5 million views of our digital videos in 2019. We also estimate that visits to our website were 300,000 in 2019 and searches of our website for physicians capable of placing our Obalon Balloon System were over 43,000 in 2019. We also generated over 20,000 patient leads to our physician partners and the Obalon Center for Weight Loss™ treatment center in the United States during 2019. There was a significant reduction in spending for digital, offline and social marketing in the second quarter of 2019 due to the change in commercialization efforts. In the third quarter of 2019 we initiated digital marketing programs in support of the Obalon Center for Weight Loss™ treatment center.

We generated total revenue of $3.3 million and $9.1 million for the years ended December 31, 2019 and 2018, respectively. For the years ended December 31, 2019 and 2018, our net loss was $23.7 million and $37.4 million, respectively. We have not been profitable since inception, and as of December 31, 2019, our accumulated deficit was $172.4 million. From inception through December 31, 2019, 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.

In August 2019, we issued and sold an aggregate of (i) 2,427,500 shares of our common stock, (ii) pre-funded warrants to purchase up to 1,735,000 shares of common stock, (iii) accompanying warrants to purchase up to 3,234,375 shares of common stock and (iv) an additional warrant to the underwriters for the purchase 37,500 shares of 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. The offering was made pursuant to a registration statement on Form S-1. As of December 31, 2019, we had cash and cash equivalents of $14.1 million. During the second quarter of 2019, we paid down $15.0 million of the principal balance due under our loan and security agreement with Pacific Western Bank (as successor-in-interest to Square 1 Bank) and during the third quarter of 2019, we paid down the remaining $5.0 million of principal balance due under the loan and security agreement, thereby removing the risks and restrictions of carrying long-term debt.

In an effort to address our liquidity concerns, on April 2, 2019, we commenced an internal restructuring and notified approximately 49 employees, or approximately 50% of our workforce, that their employment would be terminated. This restructuring included the elimination of our field sales force and a transition to more centralized customer support and marketing program strategy. Going forward, rather than focusing on selling to physicians, we intend to focus our commercialization efforts on the establishment and operation of Company-owned or managed Obalon-branded retail treatment centers.

Our consolidated financial statements as of and for the year ended December 31, 2019 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. Based on our cash balances and recurring losses since inception, there is substantial doubt about our ability to continue as a going concern and if we are not able to continue to raise sufficient capital, we will not be able to support ongoing operations.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Revenue

For fiscal years 2019 and 2018, 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 Middle East distributors, and sales from patients treated at our Company-managed Obalon-branded retail center.

Prior to December 31, 2016, all of our sales were outside the United States. In January 2017, we shifted our focus to commercialization efforts in the United States and recognized our initial U.S. revenue. We will continue to focus on selling our Obalon Balloon System in the United States, which we anticipate to be our primary market. However, in the fourth quarter of 2019, we recognized revenue from the sale of product to an international distributor. In April 2019, we restructured operations and eliminated the field sales force, and transitioned to a centralized customer support model to support our physician customers. To date we have experienced limited penetration of the U.S. market, and the degree to which our revenue will increase depends on many factors, including our ability to develop the Company-owned or managed Obalon-branded treatment center model, our ability to develop the intragastric balloon market (which is currently small and immature), 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, 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 the customer incentive programs we decide to offer and the channels through which the revenue is derived.

In January 2017, we began offering a swallow guarantee program to our physician customers in the United States through which we may provide replacement balloons to physicians and institutions when patients are unsuccessful in swallowing an Obalon balloon, subject to certain requirements and restrictions. We defer revenue relating to this swallow guarantee program based on expected failure rate and then recognize the revenue when replacement balloons are provided. As a result of this program our financial results or gross profit may be adversely impacted.

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. We expect cost of revenue to increase at a higher rate with U.S. commercialization of the Obalon Navigation System due to higher costs associated with capital equipment, including the Obalon Navigation System Console and Obalon Touch Inflation Dispenser, and inefficiencies associated with manufacturing scale up for our new Obalon Navigation balloon and related components. Longer term, we expect cost of revenue to increase in absolute dollars to the extent our revenue grows but decrease as a percentage of revenue over time as the fixed portion of our overhead costs is allocated over a greater number of units produced.

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 our gross margin to increase over the long term as our production volume increases, and as we allocate the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby reducing our per unit manufacturing costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs per unit and increase our gross margin. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter as we adopt new manufacturing processes and technologies, continue to introduce new products, expand manufacturing capacity when required, discontinue obsolete products and enter international markets. We have experienced challenges in our ability to produce finished goods and we may not be able to meet commercial demand. While we have taken steps to address these challenges, we cannot assure you those steps will be sufficient or that additional challenges will not arise as we continue with the commercialization of our Obalon Balloon System including the Obalon Navigation System and Obalon Navigation balloon.

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 in 2019 compared to 2018 due to overall headcount reductions and elimination of significant one-time charges executed in the second quarter of 2019, but could increase in absolute dollars in subsequent years in part due to the opening of new Company-owned or managed retail treatment centers. SG&A expenses are expected to vary as a percentage of total revenue for the foreseeable future.

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.

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 $1.2 million and $1.3 million, respectively, during the first quarter of 2019.

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,	
	2019	2018
Consolidated statements of operations data:		
Revenue	$ 3,281	$ 9,101
Cost of revenue	2,950	5,423
Gross profit	331	3,678
Operating expenses:		
Research and development	6,893	10,697
Selling, general and administrative	16,668	29,946
Total operating expenses	23,561	40,643
Loss from operations	(23,230)	(36,965)
Interest expense, net	(385)	(226)
Other expense, net	(61)	(189)
Net loss	(23,676)	(37,380)
Other comprehensive income (loss)	—	5
Net loss and comprehensive loss	$ (23,676)	$ (37,375)

Comparison of years ended December 31, 2019 and 2018

Revenue. Revenue decreased $5.8 million to $3.3 million during the year ended December 31, 2019, compared to $9.1 million during the year ended December 31, 2018. During the second quarter of 2019, we fundamentally changed our commercialization efforts and restructured operations, eliminating the field sales force and transitioning 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. As a result, revenue from U.S sales decreased $2.3 million stemming from selling fewer balloons in the U.S. Furthermore, sales to our Middle East distributors declined $3.5 million over 2018 sales outside the U.S.

Cost of revenue and gross profit. Cost of revenue decreased $2.4 million to $3.0 million during the year ended December 31, 2019, compared to $5.4 million during the year ended December 31, 2018. The decrease in cost of revenue was primarily driven by the Company's shift towards the new retail center business model, which included reducing the volume of product sold to physicians and institutions. As a result of this change in strategy and reduced sales, we recognized a decrease to standard cost of revenue of $2.1 million as well as a decrease of $1.1 million in scrap, QA sampling, and excess and obsolete inventory reserve. In addition the April 2019 internal restructuring also resulted in a decrease of $1.4 million in labor expense. This was partially offset by an increase to inventory absorption of $2.2 million. Gross profit decreased $3.4 million to $0.3 million during the year ended December 31, 2019, compared to $3.7 million during the year ended December 31, 2018. Gross margin decreased to 10.1% during the year ended December 31, 2019, compared to 40.4% during the year ended December 31, 2018.

Research and development expenses. R&D expenses decreased $3.8 million to $6.9 million during the year ended December 31, 2019, compared to $10.7 million during the year ended December 31, 2018. This decrease was primarily due to a decrease of $2.1 million in payroll related expenses and a decrease of $0.4 million in stock-based compensation expense both resulting from the April 2019 internal restructuring, a decrease of $0.6 million in costs associated with the development of the Obalon Navigation System which occurred during 2018, a decrease of $0.5 million in clinical trial expenses, a decrease of $0.1 million in travel expenses, and a decrease of $0.1 million due to a loss on fixed asset disposal which occurred during 2018.

Selling, general and administrative expenses. SG&A expenses decreased $13.2 million to $16.7 million during the year ended December 31, 2019, compared to $29.9 million during the year ended December 31, 2018. This decrease was primarily attributable to a decrease of $5.7 million in marketing and advertising related expenses due to the shift in operations and change in business strategy, a decrease of $5.5 million in payroll related expenses, a decrease of $1.1 million in stock-based compensation expense, and a decrease of $1.1 million in variable compensation all related to the April 2019 internal restructuring. Furthermore, there was a decrease of $0.6 million in bad debt expense, and a decrease of $0.5 million in in legal, accounting fees and other charges incurred related to the investigation by our audit committee of whistleblower allegations utilizing outside counsel and a forensic accounting firm and securities litigation costs. The overall decrease was partially offset by an increase of $1.0 million in consulting fees associated with the change in business strategy as well as an increase of $0.3 million in general business expenses.

Interest expense, net. Interest expense, net increased $0.2 million to $0.4 million during the year ended December 31, 2019, compared to $0.2 million during the year ended December 31, 2018. This increase was attributable to the draw down of $10.0 million in February 2019, which resulted in increased interest expense on outstanding debt during the year ended December 31, 2019 compared to the prior year period.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2019, we had cash and cash equivalents of $14.1 million and an accumulated deficit of $172.4 million. Our primary sources of capital have been private placements of preferred stock, the sale of common stock in our IPO, and in subsequent public and private placements, and, to a lesser extent, the incurrence of debt. In August 2019, we raised $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by us in a public offering of common stock and warrants. Additionally, during the second quarter of 2019, we paid down $15.0 million of the principal balance due under the loan and security agreement with Pacific Western Bank (as successor-in-interest to Square 1 Bank). During the third quarter of 2019, we paid the remaining $5.0 million of principal balance due under our loan and security agreement, thereby removing the risks and restrictions of carrying long-term debt.

Notwithstanding our recent financings, our current cash level raises substantial doubt about our ability to continue as a going concern and if we are not able to continue to raise sufficient capital, we will not be able to support ongoing operations.

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 is 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, 2019.

Securities Purchase Agreement

On May 23, 2019, we entered into a Securities Purchase Agreement with certain investors for the sale of 500,000 shares of our 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 aggregate gross proceeds for the sale of the shares was $3.0 million.

Equity Distribution Agreement

On December 27, 2018, we entered into the Equity Distribution Agreement, with Canaccord, pursuant to which we may, from time to time, sell shares of our common stock, having an aggregate offering price of up to $10.0 million through Canaccord, as our sales agent. Any shares sold pursuant to the Equity Distribution Agreement will be freely tradeable unless purchased by one of our affiliates.

We will pay 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 us and indemnification obligations of us and Canaccord as well as certain termination rights for both us and Canaccord. We have no obligation to sell any 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 our common stock held by non-affiliates, or public float, is greater than $75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under our ATM program, is limited to an aggregate of one-third of our public float.

As of December 31, 2019, the Company 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, we entered into a Purchase Agreement and Registration Rights Agreement, with Lincoln Park Capital Fund LLC, or Lincoln Park, pursuant to which we had the right, but not the obligation, to sell Lincoln Park, and Lincoln Park was obligated to purchase up to $20.0 million of our common stock, over the 36-month period that commenced in February 2019. We issued to Lincoln Park 22,818 shares of common stock as commitment shares in consideration for entering into the purchase agreement. As of December 31, 2019, we sold 356,122 shares under the Lincoln Park Purchase Agreement for aggregate gross proceeds of $4.2 million.

In February 2020, we terminated the prior agreement with Lincoln Park and entered into a new Purchase Agreement with Lincoln Park pursuant to which Lincoln Park has committed to purchase up to $15.0 million of our common stock over a 36-month period.

See Note 13 for further details.

Loan and security agreement

In June 2013, we 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 we subsequently amended in October 2014, September 2016, December 2016, June 2017 and July 2018.

In July 2018, we 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 of $10.0 million funded on July 10, 2018, of which the full $10.0 million was required to be used to settle the existing debt with Pacific Western Bank on a net settlement basis (pursuant to its original terms); and a second tranche of an additional $10.0 million which could be drawn at any time prior to July 9, 2019. During the first quarter of 2019, we drew down on the remaining $10.0 million tranche and in the second quarter of 2019, we repaid $15.0 million of the principal balance due under the loan and security agreement with Pacific Western Bank (as successor-in-interest to Square 1 Bank). In the third quarter of 2019, we paid the remaining $5.0 million of principal balance due under the loan and security agreement with Pacific Western Bank, removing the risks and restrictions of carrying long-term debt.

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.

Additional Capital Requirements

We expect to incur substantial expenditures in the next twelve months to continue developing the immature intragastric balloon market, support the U.S. commercialization of our product and to support continued research and development. In particular, we expect our costs and expenses to increase in the future as we continue (i) U.S. commercialization of our product, including our efforts to expand the number of Obalon-branded retail treatment centers, incur costs associated with a centralized customer support strategy, and other efforts to develop the immature intragastric balloon market and (ii) research and development, including conducting clinical trials of our products in development. Additionally, we expect to continue to incur substantial costs as a result of operating as a public company. We believe there is substantial doubt about our ability to continue as a going concern and if we are not able to continue to raise sufficient capital, we will not be able to support ongoing operations. The accompanying consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

In an effort to address these liquidity concerns, on April 2, 2019, we commenced an internal restructuring and notified approximately 49 employees, or approximately 50% of our workforce, that their employment would be terminated. This restructuring included the elimination of our field sales force and a transition to a more centralized customer support model for our existing physician customers. Going forward, rather than focusing on selling to physicians, we intend to focus our commercialization efforts on the establishment and operation of Company-owned or managed Obalon-branded retail treatment centers. We are in the early stages of this transition and cannot predict whether it will be an effective means of selling the Obalon Balloon System.

Our ability to continue as a going concern, and correspondingly to execute on our business plan and strategy, is dependent upon our ability to accomplish one or more of the following: raise additional capital in the very near term to fund our ongoing operations or engage in a strategic alternative.

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,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	$ (22,866)	(29,432)
Investing activities	2,356	19,517
Financing activities	13,378	9,994
Net (decrease) increase in cash and cash equivalents	$ (7,132)	$ 79

Net cash used in operating activities

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, an increase 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.

During the year ended December 31, 2018, net cash used in operating activities was $29.4 million, consisting primarily of a net loss of $37.4 million, partially offset by a decrease in net operating assets of $2.6 million primarily related to a decrease in accounts receivable, partially offset by an increase in accrued compensation. These items were partially offset by non-cash charges of $5.4 million, consisting primarily of stock-based compensation expense.

Net cash provided by investing activities

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 capital expenditures.

During the year ended December 31, 2018, net cash provided by investing activities was $19.5 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, 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.

During the year ended December 31, 2018, net cash provided by financing activities was $10.0 million, consisting primarily of proceeds from issuance of common stock (net of issuance costs) of $9.8 million and proceeds from purchases of common stock pursuant to our Employee Stock Purchase Plan.

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, 2019, 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, 2019. 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, 2019.

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, 2019, 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, 2019 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 2020 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 2020 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 2020 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 2020 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 2020 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:

	Page(s)
Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	79
Consolidated Balance Sheets as of December 31, 2019 and 2018	80
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2019 and 2018	81
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2019 and 2018	82
Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018	83
Notes to Consolidated Financial Statements	84

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

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Obalon Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period 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 2018, and the results of its operations and its cash flows for each of the years in the two-year period 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.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)*, and the related amendments.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

San Diego, California
February 27, 2020

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

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 14,055	$ 21,187
Short-term investments	—	2,548
Accounts receivable, net	285	870
Inventory	1,936	1,580
Other current assets	1,959	2,462
Total current assets	18,235	28,647
Lease right-of-use assets	1,077	—
Property and equipment, net	1,081	1,739
Total assets	$ 20,393	$ 30,386
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 648	$ 1,159
Accrued compensation	820	3,805
Deferred revenue	424	352
Other current liabilities	1,524	1,985
Current portion of lease liabilities	561	—
Current portion of long-term loan	—	9,930
Total current liabilities	3,977	17,231
Lease liabilities long-term	567	—
Other long-term liabilities	—	48
Total liabilities	4,544	17,279
Commitments and contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2019 and December 31, 2018; 7,724,100 and 2,351,333 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	8	2
Additional paid-in capital	188,271	161,859
Accumulated deficit	(172,430)	(148,754)
Total stockholders' equity	15,849	13,107
Total liabilities and stockholders' equity	$ 20,393	$ 30,386

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,	
	2019	**2018**
Revenue:		
Revenue	$ 3,281	$ 9,101
Total revenue	3,281	9,101
Cost of revenue	2,950	5,423
Gross profit	331	3,678
Operating expenses:		
Research and development	6,893	10,697
Selling, general and administrative	16,668	29,946
Total operating expenses	23,561	40,643
Loss from operations	(23,230)	(36,965)
Interest expense, net	(385)	(226)
Other expense	(61)	(189)
Net loss	(23,676)	(37,380)
Other comprehensive income	—	5
Net loss and comprehensive loss	$ (23,676)	$ (37,375)
Net loss per share, basic and diluted	$ (5.03)	$ (19.64)
Weighted-average common shares outstanding, basic and diluted	4,706,775	1,903,734

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 other comprehensive (loss) income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2017	1,750,061	$ 2	$ 146,490	$ (5)	$ (111,374)	$ 35,113
Stock-based compensation	—	—	4,693	—	—	4,693
Issuance of common stock for cash upon exercise of stock options	4,582	—	53	—	—	53
Vesting of early exercised stock options	—	—	57	—	—	57
Issuance of common stock under ESPP	4,526	—	148	—	—	148
Issuance of common stock, net of issuance costs	572,269	—	10,418	—	—	10,418
Issuance of restricted stock awards, net of cancellations	19,895	—	—	—	—	—
Unrealized gain on short term investments	—	—	—	5	—	5
Net loss	—	—	—	—	(37,380)	(37,380)
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

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2019	**2018**
Operating activities:		
Net loss	$ (23,676)	$ (37,380)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	479	581
Stock-based compensation	2,983	4,693
Amortization of right-of-use asset	415	—
Loss on disposal of fixed assets	128	107
Accretion of investment discount, net	(2)	(50)
Amortization of debt discount	70	37
Change in operating assets and liabilities:		
Accounts receivable, net	585	3,353
Inventory	12	(162)
Other current assets	411	98
Accounts payable	(543)	70
Accrued compensation	(2,985)	(689)
Deferred revenue	72	(158)
Lease liabilities, net	(364)	—
Other current and long-term liabilities	(451)	68
Net cash used in operating activities	(22,866)	(29,432)
Investing activities:		
Purchases of short-term investments	—	(9,102)
Maturities of short-term investments	2,550	29,901
Purchases of property and equipment	(194)	(1,282)
Net cash provided by investing activities	2,356	19,517
Financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	23,377	9,823
Proceeds from long-term loan, net of issuance costs	10,000	—
Fees paid in connection with fifth amendment to loan and security agreement	—	(30)
Repayments of long-term loans	(20,000)	—
Proceeds from common stock issued under employee stock purchase plan	—	148
Proceeds from sale of common stock upon exercise of stock options	1	53
Net cash provided by financing activities	13,378	9,994
Net (decrease) increase in cash and cash equivalents	(7,132)	79
Cash and cash equivalents at beginning of period	21,187	21,108
Cash and cash equivalents at end of period	$ 14,055	$ 21,187
Supplemental cash flow information:		
Interest paid	$ 719	$ 642
Income taxes paid	$ —	$ 7
Property and equipment in accounts payable	$ 32	$ 201
Unpaid issuance costs	$ —	$ 250
Fair value of commitment shares issued	$ —	$ 595

See accompanying 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, 2019, 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 $3.3 million and $9.1 million for the years ended December 31, 2019 and 2018, 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, 2019, its accumulated deficit was $172.4 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 expects to continue to incur net losses for the foreseeable future as it continues to launch Obalon-branded retail centers, and continues research and development efforts. As a result, there is substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance date of the consolidated financial statements for the year ended December 31, 2019.

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 obtain sufficient funds on acceptable terms could have a material adverse effect on the Company's business, results of operations or financial condition.

In August 2019, the Company issued and sold an aggregate of (i) 2,427,500 shares of its 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, (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) and (iv) an additional warrant to the underwriters for the purchase 37,500 shares of common stock, for net proceeds from the offering of approximately $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. As of December 31, 2019, the Company had cash and cash equivalents of $14.1 million. Additionally, during the second quarter of 2019, the Company paid down $15.0 million of the principal balance due under the loan and security agreement with Pacific Western Bank (as successor-in-interest to Square 1 Bank) and during the third quarter of 2019, the Company paid down the remaining $5.0 million of principal balance due under the loan and security agreement with Pacific Western Bank, thereby removing the risks and restrictions of carrying long-term debt. See Note 8 for further detail regarding the equity financing transactions.

In an effort to address the Company's liquidity concerns, and pay expenses relating to its operating activities, including selling, general and administrative expenses and research and development expenses, on April 2, 2019, the Company commenced an internal restructuring and notified approximately 49 employees, or approximately 50% of the Company's workforce, that their employment was terminated. This restructuring included the elimination of the Company's field sales force and a transition to more centralized customer support and marketing program strategy. Going forward, rather than focusing on selling to physicians, the Company has focused its commercialization efforts on the establishment and operation of Company-owned or managed Obalon-branded retail treatment centers. See Note 12 for further details regarding the restructuring activities.

The Company plans to use proceeds from the August 2019 public offering, equity distribution agreement and the Lincoln Park purchase agreement to the extent needed to fund operations. If the Company is unable to execute against its strategic plan, the Company may be required to delay the development of one or more of their products, delay clinical trials necessary to market their products, or delay establishment or expansion of sales and marketing capabilities. See Note 8 for further detail regarding the 2019 equity financing transactions.

Equity Distribution Agreement

In December 2018, the Company entered into an 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, par value $0.001 per share (the "ATM Shares"), having an aggregate offering price of up to $10 million through Canaccord, as its sales agent.

Lincoln Park Purchase Agreement

In February 2020, the Company entered into a new purchase agreement with Lincoln Park Capital Fund, LLC. See Note 13 for further details.

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.

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 $0.5 million and $0.7 million at December 31, 2019 and 2018, 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	2019	2018
Customer A	19.7 %	3.4 %
Customer B	17.9 %	48.4 %
Customer C	— %	14.1 %

Accounts Receivable	December 31, 2019	December 31, 2018
Customer A	20.8 %	2.1 %
Customer B	— %	— %
Customer C	— %	0.7 %

The Company's largest customer for the year ended December 31, 2019 was a U.S. physician, and for the year ended December 31, 2018 the largest customer was its Middle East distributor in Kuwait.

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.

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. The Company did not recognize any material impairment losses for the respective years ended December 31, 2019 and 2018.

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, 2019. The current and long-term portions of finance lease liabilities are presented within the current portion of lease liabilities and lease liabilities long-term line items on the consolidated balance sheet, respectively. Finance 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, 2019 and 2018 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, 2019 and 2018 were approximately $0.8 million and $3.8 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.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under this new guidance, at the commencement date, lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. This guidance is not applicable for leases with a term of 12 months or less. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842 (Leases), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2018, with early adoption permitted. In July 2018, the FASB issued ASU No. 2018-11, Leases Topic (842): Targeted Improvements. This ASU provides companies an option to apply the transition provisions of the new lease standard at its adoption date instead of at the earliest comparative period presented in its financial statements. The Company elected the optional method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption, if needed, and did not restate prior periods. The Company elected certain practical expedients permitted under the transition guidance. As part of the adoption, the Company recorded a ROU asset and liability upon adoption of the guidance pertaining to its long-term real estate lease for its corporate facilities. No cumulative-effect adjustment was needed.

In February 2018, the FASB issued Accounting Standards Update ("ASU") 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220). The new guidance permits, but does not require, companies to reclassify the stranded tax effects of the Tax Cuts and Jobs Act on items within accumulated other comprehensive income to retained earnings. The Company adopted this standard in the first quarter of 2019, which did not have a material impact on its 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 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 will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. The Company is currently evaluating this guidance to determine the impact, if any, it may have 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, 2019 and 2018 are as follows (in thousands):

	Balance as of December 31, 2019	Fair value measurements at reporting date using: 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	$ —	$ —

	Balance as of December 31, 2018	Fair value measurements at reporting date using: Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash	$ 18,384	$ 18,384		
Cash Equivalents:				
Money Market Funds	2,803	2,803	—	—
Short-term investments:				
U.S. Treasury bonds	2,548	2,548	—	—
Total assets	$ 23,735	$ 23,735	$ —	$ —

The Company’s investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as of December 31, 2019 and 2018.

Instruments Not Recorded at Fair Value on a Recurring Basis

The estimated fair value of the Company's long-term loan as of December 31, 2018 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 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, 2019	Year ended December 31, 2018
Net loss	$ (23,676)	$ (37,380)
Weighted-average common shares outstanding, basic and diluted	4,706,775	1,903,734
Net loss per share, basic and diluted	$ (5.03)	$ (19.64)

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,	
	2019	2018
Stock options to purchase common stock	8,900	38,352
Total	8,900	38,352

5. Balance Sheet Details

Inventory consists of the following (in thousands):

	December 31,	
	2019	2018
Raw materials	$ 1,835	$ 1,090
Work in process	12	288
Finished goods	89	202
Total	$ 1,936	$ 1,580

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

	December 31,	
	2019	2018
Prepaid expenses	$ 1,890	$ 2,329
Interest receivable	0	12
Other assets	69	121
Total	$ 1,959	$ 2,462

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

	December 31,	
	2019	2018
Computer hardware	$ 263	$ 410
Computer software	291	274
Leasehold improvements	497	405
Furniture and fixtures	247	178
Scientific equipment	1,999	1,921
Construction in progress, or CIP	110	530
	3,407	3,718
Less: accumulated depreciation	(2,326)	(1,979)
Total	$ 1,081	$ 1,739

Depreciation expense for the years ended December 31, 2019 and 2018 was $0.5 million and $0.6 million for each period, respectively.

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

	December 31,	
	2019	2018
Accrued legal and professional fees	$ 412	$ 624
Accrued customer incentives	198	467
Accrued sales and other taxes	107	132
Returns reserve liability	315	214
Other accrued expenses	492	548
Total	$ 1,524	$ 1,985

6. Term Loan

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, 2019, 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.

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 223,673 shares of common stock for issuance as of January 1, 2019 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. At December 31, 2019, 5,337 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,	
	2019	2018
Cost of revenue	$ (21)	$ 96
Research and development	739	1,141
Selling, general and administrative	2,265	3,456
Total	$ 2,983	$ 4,693

Unrecognized stock-based compensation expense at December 31, 2019 for all stock-based compensation pertaining to options was approximately $1.7 million. Expense associated with all stock-based compensation is expected to be recognized over a weighted-average term of 2.4 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,	
	2019	2018
Assumed risk-free interest rate (1)	1.67% - 2.58%	2.31% - 3.10%
Assumed volatility (2)	55.07% - 65.21%	53.95% - 55.44%
Expected option life (3)	6.1 years	5.0 - 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, 2019

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

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2018	336,008	$ 58.29		
Options granted	237,197	12.13		
Options exercised	(118)	8.72		
Options canceled	(54,619)	44.46		
Outstanding at December 31, 2019	518,468	38.64	6.8	$ 12
Vested and expected to vest at December 31, 2019	475,431	$ 40.60	6.6	$ 9
Vested and exercisable at December 31, 2019	270,613	$ 52.72	6.1	$ 0.3

The weighted-average fair value of options granted during the year ended December 31, 2019 was $6.81. The intrinsic value of options exercised for the years ended December 31, 2019 and 2018 was immaterial and $0.1 million, respectively.

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, 2019 and 2018. For prior early exercised options, 1,383 shares remain unvested with an immaterial related liability recorded under other current liabilities on the Company's consolidated balance sheet as of December 31, 2019.

Restricted Stock Awards

The following table summarizes restricted stock award transactions for the year ended December 31, 2019:

	Number of awards	Weighted-average grant date fair value
Outstanding at December 31, 2018	61,198	$ 58.85
Awards granted	—	—
Awards released	(4,750)	71.50
Awards canceled	(26,924)	77.70
Outstanding at December 31, 2019	29,524	$ 39.64

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 1.5 years.

Restricted Stock Units

The following table summarizes restricted stock unit transactions for the 2016 Plan for the year ended December 31, 2019:

	Number of shares	Weighted-average grant date fair value	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2018	—	$ —	
Awards granted	55,574	11.70	
Awards released	—	—	
Awards canceled	—	—	
Outstanding at December 31, 2019	55,574	$ 11.70	$ 106
Vested and expected to vest at December 31, 2019	51,894	$ 11.84	$ 99

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. Unamortized expense of $0.2 million is expected to be recognized over a weighted-average period of 0.6 years.

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. 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, 2019, and 4,526 shares of common stock issued during the year ended December 31, 2018 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 2019. None of the Purchase or Representative Warrants have been exercised as of December 31, 2019. 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 was $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 condensed 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 form 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 the 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.

In February 2020, the Company entered into a new purchase agreement and registration rights agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15.0 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. Please see Note 13 for further details.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2019:

Stock options issued and outstanding	518,468
Restricted stock units issued and outstanding	55,574
Warrants for the purchase of common stock	3,271,875
Authorized for future option and ongoing vesting of award grants	5,337
Authorized for future issuance under ESPP	74,520
Total	3,925,774

9. Income Taxes

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

	Year ended December 31,	
	2019	2018
Current:		
Federal	$ —	$ —
State	14	11
Total current provision	14	11
Deferred:		
Federal	—	—
State	—	—
Total deferred provision	—	—
Income tax provision	$ 14	$ 11

The difference between income tax benefits and income taxes computed using the U.S. federal income tax rate as of December 31, 2019 and 2018 are as follows (in thousands):

	Year ended December 31,	
	2019	2018
Federal provision (benefit)		
At statutory rates	$ (4,971)	$ (7,848)
Change in valuation allowance	4,985	7,859
Income tax provision	$ 14	$ 11

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

	Year ended December 31,	
	2019	2018
Deferred tax assets:		
Net operating losses	$ 35,252	$ 28,708
Tax credits	5,493	4,898
Capitalized research and development costs	2,401	2,566
Other	2,724	2,458
Total gross deferred tax assets	45,870	38,630
Less valuation allowance	(45,578)	(38,630)
Total deferred tax assets	$ 292	$ —
Deferred tax liabilities:		
Other	$ (292)	$ —
Total deferred tax liabilities	$ (292)	$ —

A valuation allowance of $45.6 million and $38.6 million as of December 31, 2019 and 2018, respectively, has been established to offset the deferred tax assets as realization of such assets are uncertain.

At December 31, 2019, the Company had federal and state net operating loss carryforwards of approximately $147.9 million and $114.6 million, respectively. The federal and state tax loss carryforwards will begin expiring in 2028, unless previously utilized. The federal net operating loss carryover includes $59.7 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. The Company conducts research and experimentation activities, generating research tax credits for federal and state purposes under IRC Section 41. The Company has not performed a formal study validating these credits claimed in the tax returns. Once a study is prepared, the amount of R&D tax credits available could vary from what was originally claimed on the tax returns.

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. 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, 2019 and 2018, the Company had unrecognized tax benefits of $4.3 million and $3.6 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,	
	2019	2018
Balance at January 1	$ 3,609	$ 2,128
Additions based on tax positions related to current year	643	1,513
Additions based on tax positions related to prior years	—	—
Reductions for tax positions related to prior years	(2)	(32)
Balance at December 31	$ 4,250	$ 3,609

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.

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 2021 and 2022. 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. 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. 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, 2019 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.

Future minimum annual lease payments under such leases were as follows as of December 31, 2019 (in thousands):

Operating leases:		
2020	$	537
2021		517
2022		117
Total undiscounted lease payments - operating leases	$	1,171
Finance leases:		
2020	$	24
2021		24
Total undiscounted lease payments - finance leases	$	48
Total undiscounted lease payments	$	1,219
Less: imputed interest	$	(91)
Lease liability	$	1,128
Less: current portion of lease liability	$	(561)
Lease liability, less current portion	$	567

As of December 31, 2019, the Company's remaining lease terms range from 1.6 to 2.3 years . Rent expense totaled and $0.6 million and $0.4 million for the year ended December 31, 2019 and 2018, respectively. The Company paid $0.5 million of cash payments related to its operating lease agreement for the year ended December 31, 2019.

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.

Pursuant to the Company's supplier agreement entered into in December 2018, the Company is obligated to purchase certain minimum quantities. These costs scale up as the Company's projected manufacturing volume increases. Under the terms of the agreement, the

Company can reduce the forecasted minimum quantities and is required to incur a holding fee for items manufactured by the supplier. This represents the one year minimum commitment of approximately $0.5 million as of December 31, 2019.

Termination of Stock Offering

On January 23, 2018, the Company issued a press release announcing the termination of its previously announced offering of common stock due to a purported whistleblower compliant, which was later found to be without merit. As of December 31, 2019, the Company did not record any liability associated with termination of the offering, and management believed that the likelihood is remote that the Company will incur material fees in the future.

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. The Company believes the remaining claims in the complaint are without merit and intend to defend vigorously against them.

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 condensed consolidated financial statements.

For the year ended December 31, 2019, the PC recognized $0.2 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, 2019.

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 $0.3 million has been paid as of December 31, 2019. 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

13. Subsequent Events

Equity Incentive Plan Restricted Stock Unit Awards

On January 24, 2020, the Compensation Committee of the Company approved grants of restricted stock units under the 2016 Plan. Such restricted stock units were granted to certain executives at the Company in an aggregate amount of 816,081 restricted stock units, and may be settled in cash or stock in accordance with the terms of the awards. Each award will fully vest on the earlier of (i) December 31, 2022 and (ii) the consummation of a corporate transaction (as defined in the applicable award agreement), in each case, based on the achievement of stock price goals on the vesting date, subject to the executive's continued service with the Company through the vesting date.

Treatment Centers - Orange County, CA and Sacramento, CA

On January 24, 2020, the Company entered into a lease agreement with 1640 Newport Blvd. LP pursuant to which the Company has agreed to lease office space located in Orange County, at 1640 Newport Blvd. Costa Mesa, CA. The Company took possession of the office space on January 31, 2020, with the term of the lease agreement ending 62 months after such date, unless terminated earlier. The facility opened in February 2020. This facility serves as the second Obalon-branded treatment center location.

On January 30, 2020, the Company entered into a lease agreement with Daniel L and Lyn S Monahan Trust pursuant to which the Company has agreed to lease office space located near Sacramento, at 1211 Pleasant Grove, Suite 100, Roseville, CA 95678. The lease commenced on February 1, 2020, with the term of the lease agreement ending 64 months after such date, unless terminated earlier.

Lincoln Park Capital Fund, LLC Equity Line of Credit

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 the 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, is declared effective by the SEC and a final prospectus in connection therewith is filed and the other conditions set forth in the purchase agreement are satisfied (such date on which all of such conditions are satisfied, the “Commencement Date”).

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: February 27, 2020 by: /s/ William Plovanic

President and Chief Executive Officer
(Principal Executive Officer)

Date: February 27, 2020 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 William Plovanic 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/ William Plovanic **William Plovanic**	President and Chief Executive Officer and Director (Principal Executive Officer)	Date: February 27, 2020
/s/ Nooshin Hussainy **Nooshin Hussainy**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	Date: February 27, 2020
/s/ Andrew Rasdal **Andrew Rasdal**	Chairperson of the Board of Directors	Date: February 27, 2020
/s/ Kim Kamdar **Kim Kamdar**	Director	Date: February 27, 2020
/s/ Ray Dittamore **Ray Dittamore**	Director	Date: February 27, 2020
/s/ Douglas Fisher **Douglas Fisher**	Director	Date: February 27, 2020
/s/ Les Howe **Les Howe**	Director	Date: February 27, 2020
/s/ David Moatazedi **David Moatazedi**	Director	Date: February 27, 2020
/s/ Sharon Stevenson **Sharon Stevenson**	Director	Date: February 27, 2020

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	
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	
4.3	Form of Warrant to Purchase Series C Preferred Stock	S-1	9/9/16	4.3	
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				X
4.9	Form of Pre-Funded Warrant	S-1/A	8/1/19	4.5	
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‡	2016 Equity Incentive Plan and form of award agreements thereunder	S-1	9/26/16	10.3	
10.4‡	First Amendment to 2016 Equity Incentive Plan	10-K	2/22/19	10.4	

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-Q	8/2/17	10.2	
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	
10.16‡	Offer Letter dated August 14, 2017 between the Company and Kelly Huang	10-K	3/5/18	10.14	
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	
10.26	Purchase Agreement dated December 27, 2018, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	12/27/18	10.1	
10.27	Registration Rights Agreement dated December 27, 2018, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	12/27/18	10.2	
10.28‡	Form of Restricted Stock Unit Award pursuant to the 2016 Equity Incentive Plan				X
10.29‡*	Consulting Agreement dated May 20, 2019 between the Company and Kelly Huang	10-Q	7/24/19	10.1	
10.30‡*	Offer Letter dated May 26, 2019 between the Company and Robert MacDonald	10-Q	7/24/19	10.2	
10.31‡*	Offer Letter dated November 15, 2011 between the Company and Nooshin Hussainy	S-1	2/7/20	10.31	
10.32	Form of Securities Purchase Agreement	8-K	5/28/19	10.1	
10.33‡*	Form of Restricted Stock Unit Award Agreement (Share and Cash Settlement) pursuant to the 2016 Equity Incentive Plan				X

10.34	Purchase Agreement, dated February 5, 2020, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	2/7/20	10.1	
10.35	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	
21.1	Subsidiaries of the Registrant.				X
23.1	Consent of Independent Registered Public Accounting Firm				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 4.8

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of Obalon Therapeutics, Inc.'s securities is a summary. This summary is qualified by reference to the Delaware General Corporation Law (the "DGCL") and the complete text of Obalon Therapeutics, Inc.'s restated certificate of incorporation, as amended (the "Charter") and amended and restated bylaws (the "Bylaws"). We urge you to read that law and those documents carefully.

Common Stock

General. Our Charter authorizes 100,000,000 shares of common stock, $0.001 par value per share.

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors. We do not provide for cumulative voting for the election of directors in our Charter. Accordingly, holders of a majority of the shares of our common stock are able to elect all of our directors.

Potential issuance of preferred stock. Pursuant to our Charter, our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designation, vesting, powers, preferences and relative, participating, optional or other rights, if any, of the shares of each such series and any qualifications, limitations or restrictions thereof, in each case without further vote or action by our stockholders. Although the board has no intention at the present time of issuing shares of preferred stock, the rights of holders of common stock may be materially limited or qualified by the rights of holders of preferred stock that we may issue in the future.

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

No preemptive or similar rights. Our common stock is not entitled to preemptive or subscription rights, and is not subject to conversion, redemption or sinking fund provisions. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

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

Fully Paid and Nonassessable. All outstanding shares of common stock are fully paid and nonassessable.

Common Stock Warrants

The following table sets forth information about outstanding warrants to purchase shares of our common stock as of December 31, 2019:

Class of Stock	Number of Shares	Exercise Price per Share	Expiration Date
Common Stock	3,234,375	$4.40	August 6, 2024
Common Stock	37,500	$5.00	August 6, 2024

The number of shares and exercise price information above is subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events. Each of these warrants has a cashless exercise provision under which the holder, in lieu of paying the exercise price in cash, can surrender the warrant and receive a net number of shares based on the fair market value of such stock at the time of exercise, after deducting the aggregate exercise price.

Except for rights related to stock dividends, splits, reverse splits, distributions and rights otherwise provided in the warrants or by virtue of such holder's ownership of our common stock, the holders of the warrants are not entitled to the rights or privileges of holders of our common stock, including any voting rights prior to the exercise of their warrants.

Annual Stockholder Meetings

Our Bylaws provide that annual stockholder meetings will be held at a date, place (if any) and time, as selected by the board of directors. To the extent permitted under applicable law, we may, but are not obligated to conduct meetings by remote communications.

Anti-Takeover Provisions

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

Delaware law

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

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by

written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Provisions Relating to our Charter and Bylaws

Our Charter and our Bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- *Board of Directors Vacancies.* Our Charter and Bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors will be permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

- *Classified Board.* Our Charter and Bylaws provide that our board of directors be classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

- *Stockholder Action; Special Meetings of Stockholders.* Our Charter provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our Bylaws or remove directors without holding a meeting of our stockholders called in accordance with our Bylaws. Further, our Bylaws and Charter provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- *Advance Notice Requirements for Stockholder Proposals and Director Nominations.* Our Bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our Bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

- *No Cumulative Voting.* The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our Charter does not provide for cumulative voting.

- *Directors Removed Only for Cause.* Our Charter provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.

- *Amendment of Charter Provisions.* Any amendment of the above expected provisions in our Charter would require approval by holders of at least two-thirds of our outstanding common stock, unless such amendment is approved by at least two-thirds of our directors, in which case the amendment may be approved by the holders of a majority of our outstanding common stock.

- *Amendment of Bylaw Provisions.* Any amendment of our Bylaws would require approval by a majority of the board of directors or the affirmative vote of the holders of at least two-thirds of our outstanding common stock, unless such amendment is approved by at least two-thirds of the board of directors, in which case the amendment may be approved by holders of a majority our outstanding common stock.

- *Issuance of Undesignated Preferred Stock.* Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

- *Choice of Forum.* Our Charter provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our Charter or our Bylaws; any action to interpret, apply, enforce or determine the validity of our Charter or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Stock Exchange Listing

Shares of common stock are listed on NASDAQ under the symbol "OBLN".

No Sinking Fund

The shares of common stock have no sinking fund provisions.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219.

Exhibit 10.28

NOTICE OF RESTRICTED STOCK UNIT AWARD

OBALON THERAPEUTICS, INC. 2016 EQUITY INCENTIVE PLAN

Unless otherwise defined herein, the terms defined in the Obalon Therapeutics, Inc. (the "***Company***") 2016 Equity Incentive Plan (the "***Plan***") shall have the same meanings in this Notice of Restricted Stock Unit Award (the "***Notice***") and the attached Award Agreement (Restricted Stock Unit Agreement (collectively, the "***RSU Agreement***"). You ("***you***") have been granted an award of Restricted Stock Units ("***RSUs***") under the Plan subject to the terms and conditions of the Plan, this Notice and the attached RSU Agreement.

Name:	[ ]
Address:	[ ]
Number of RSUs:	[ ]
Date of Grant:	[ ]
Vesting Schedule:	The RSUs will vest in full on January 2, 2020, subject to continued Service through such date.

You acknowledge that the vesting of the RSUs pursuant to this Notice is earned only by continuing Service. By accepting this award, you and the Company agree that this award is granted under and governed by the terms and conditions of the Plan, this Notice and the RSU Agreement. By accepting this award of RSUs, you consent to the electronic delivery and acceptance as further set forth in the RSU Agreement.

PARTICIPANT OBALON THERAPEUTICS INC.

Signature: By:
Print Name: Its:

RESTRICTED STOCK UNIT AGREEMENT

OBALON THERAPEUTICS, INC.
2016 EQUITY INCENTIVE PLAN

You have been granted Restricted Stock Units ("***RSUs***") by Obalon Therapeutics, Inc. (the "***Company***") subject to the terms, restrictions and conditions of the Plan, the Notice of Restricted Stock Unit Award (the "***Notice***") and this Restricted Stock Unit Agreement (collectively, this "***RSU Agreement***").

1. **Nature of Grant**. In accepting this award of RSUs, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the RSUs is voluntary and occasional and does not create any contractual or other right to receive future awards of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past;

(c) all decisions with respect to future RSUs or other grants, if any, will be at the sole discretion of the Company;

(d) you are voluntarily participating in the Plan;

(e) the RSUs and the Shares subject to the RSUs, and the income and value of same, are not intended to replace any pension rights or compensation;

(f) the RSUs and the Shares subject to the RSUs, and the income and value of same, are not part of normal or expected compensation for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) unless otherwise agreed with the Company, the RSUs and any Shares acquired under the Plan, and the income and value of same, are not granted as consideration for, or in connection with, any service you may provide as a director of the Company, or a Parent or Subsidiary of the Company;

(h) the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the RSUs resulting from the termination of your Service (for any reason whatsoever whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are providing Service or the terms of your employment or service agreement, if any), and in consideration of the grant of the RSUs to which you are otherwise not entitled, you irrevocably agree never to institute any claim against the Company, the Employer (as defined below), or any other Parent or Subsidiary of the Company, waive your ability, if any, to bring any such claim, and release the Company, the Employer and its Parent or Subsidiaries from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, you shall be deemed irrevocably to have agreed not to pursue such claim and agree to execute any and all documents necessary to request dismissal or withdrawal of such claim; and

(j) the following provisions apply only if you are providing Service outside the United States: (i) the RSUs and the Shares subject to the RSUs, and the income and value of same, are not part of normal or expected compensation or salary for any purpose; and (ii) neither the Company, the Employer nor any Parent or Subsidiary of the Company shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the RSUs or the subsequent sale of any Shares acquired upon settlement.

2. **Settlement**. Subject to Section 22 hereof, the Shares subject to the RSUs will be delivered on the thirtieth (30th) day following the earliest to occur of: (i) January 2, 2022, (ii) the date of your "separation from service" from the Company within the meaning of Section 409A(a)(2)(A)(i) of the Code (a "***Separation from Service***") and (iii) the date of the occurrence of a "change of control event" (within the meaning of Section 409A (as defined below)) with respect to the Company (each, a "***Distribution Event***"). Notwithstanding anything to the contrary contained herein, the exact payment date of any RSUs shall be determined by the Company in its sole discretion (and you shall not have a right to designate the time of payment). If and to the extent that any outstanding RSUs remain unvested as of a Distribution Event (after taking into consideration any vesting which may occur in connection with the occurrence of such Distribution Event), then such RSUs will (to the extent not forfeited in connection with such distribution) be distributed to you as Restricted Stock (or a right to receive the cash equivalent thereof), and the vesting schedule that applied to such RSUs immediately prior to such distribution will continue to apply to such Restricted Stock (or cash equivalent right). Fractional Shares will not be issued.

3. **No Stockholder Rights**. Unless and until such time as Shares are issued in settlement of vested RSUs, you shall have no ownership of the Shares allocated to the RSUs and shall have no right to dividends or to vote such Shares.

4. **Dividend Equivalents**. Dividends, if any (whether in cash or Shares), shall not be credited to you.

5. **No Transfer**. RSUs may not be sold, assigned, transferred, pledged, hypothecated, or otherwise disposed of in any manner other than by will or by the laws of descent or distribution or court order or unless otherwise permitted by the Committee on a case-by-case basis.

6. **Termination**. If your Service terminates for any reason, all unvested RSUs shall be forfeited to the Company forthwith, and all rights you have to such RSUs shall immediately terminate, without payment of any consideration to you. For purposes of this award of RSUs, your Service will be considered terminated as of the date you are no longer providing Service (regardless of the reason for such termination and whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are employed or the terms of your employment or service agreement, if any) and will not be extended by any notice period mandated under local employment laws (*e.g.*, Service would not include a period of "garden leave" or similar period). In case of any dispute as to whether your termination of Service has occurred, the Committee shall have sole discretion to determine whether such termination has occurred (including whether you may still be considered to be providing Services while on a leave of absence) and the effective date of such termination.

7. **Tax Consequences**. You acknowledge that there will be certain consequences with regard to income tax, national or social insurance contributions, payroll tax, fringe benefits tax, payment on account or other tax-related items ("***Tax-Related Items***") upon settlement of the RSUs or disposition of the Shares, if any, received in connection therewith, and you should consult a tax adviser regarding your tax obligations prior to such settlement or disposition in the jurisdiction where you are subject to tax.

8. **Responsibility for Taxes**. Regardless of any action the Company or, if different, your actual employer (the "***Employer***") takes with respect to any or all Tax-Related Items withholding or required deductions, you acknowledge that the ultimate liability for all Tax-Related Items legally due by you is and remains your responsibility and that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the award, including the grant, vesting or settlement of the RSUs, the subsequent sale of Shares acquired pursuant to such settlement and the receipt of any dividends; and (2) do not commit to structure the terms of the award or any aspect of the RSUs to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You acknowledge that if you are subject to Tax-Related Items in more than one jurisdiction, the Company and/or the Employer may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to the settlement of your RSUs, you shall pay or make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Items withholding and payment on account obligations of the Company and/or the Employer, including to the extent that any Federal Insurance Contributions Act ("***FICA***") tax withholding obligations arise in connection with your RSUs prior to settlement. In this regard, you authorize the Company and/or the Employer, and their

respective agents, at their discretion, to withhold all applicable Tax-Related Items legally payable by you from your wages or other cash compensation paid to you by the Company and/or the Employer. With the Company's consent, these arrangements may also include, if permissible under local law, (a) withholding Shares that otherwise would be issued to you when your RSUs are settled, provided that the Company only withholds the amount of Shares necessary to satisfy the minimum statutory withholding amount, (b) having the Company withhold taxes from the proceeds of the sale of the Shares, either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization), (c) payment by you of an amount equal to the Tax-Related Items directly by cash, cheque, wire transfer, bank draft or money order payable to the Company, or (d) any other arrangement approved by the Company; all under such rules as may be established by the Committee and in compliance with the Company's Insider Trading Policy and 10b5-1 Trading Plan Policy, if applicable; provided, however, that if you are a Section 16 officer of the Company under the Exchange Act, then the Committee (as constituted in accordance with Rule 16b-3 under the Exchange Act) shall establish the method of withholding from alternatives (a)-(d) above, and the Committee shall establish the method prior to the taxable or withholding event. The Fair Market Value of these Shares, determined as of the effective date when taxes otherwise would have been withheld in cash, will be applied as a credit against the Tax-Related Items.

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Shares equivalent. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, you are deemed to have been issued the full number of Shares subject to the vested RSUs, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax-Related Items.

You agree to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold as a result of your participation in the Plan or the vesting and settlement of the RSUs that cannot be satisfied by the means previously described. You acknowledge that the Company has no obligation to deliver Shares to you until you have satisfied the obligations in connection with the Tax-Related Items as described in this Section.

To the extent that any FICA tax withholding obligations arise in connection with the RSUs, the Company shall accelerate the payment of a number of RSUs sufficient to satisfy (but not in excess of) such tax withholding obligations and any tax withholding obligations associated with such accelerated payment, and the Company shall withhold such amounts in satisfaction of such withholding obligations.

9. Data Privacy. You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this RSU Agreement and any other RSU grant materials by and among, as applicable, the Company, the Employer and

any other Parent or Subsidiaries, for the exclusive purpose of implementing, administering and managing your participation in the Plan.

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of stock or directorships held in the Company, details of all RSUs or any other entitlement to shares of stock awarded, canceled, exercised, vested, unvested or outstanding in your favor ("**Data**"), for the exclusive purpose of implementing, administering and managing the Plan.

You understand that Data will be transferred to the stock plan service provider as may be designated by the Company from time to time, which is assisting the Company with the implementation, administration and management of the Plan. You understand that the recipients of Data may be located in the United States or elsewhere, and that the recipients' country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that if you reside outside the United States, you may request a list with the names and addresses of any potential recipients of Data by contacting your local human resources representative. You authorize the Company, the designated broker and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer Data, in electronic or other form, for the sole purpose of implementing, administering and managing your participation in the Plan. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that if you reside outside the United States, you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. Further, you understand that you are providing the consents herein on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your employment status or service and career with the Employer will not be adversely affected. The only adverse consequence of refusing or withdrawing your consent is that the Company would not be able to grant you RSUs or other equity awards or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

10. **Acknowledgement**. The Company and you agree that the RSUs are granted under and governed by the Notice, this RSU Agreement and the provisions of the Plan. You: (i) acknowledge receipt of a copy of the Plan prospectus, (ii) represent that you have carefully read and are familiar with the provisions in the grant documents, and (iii) hereby accept the RSUs subject to all of the terms and conditions set forth in this RSU Agreement and those set forth in the Notice. You hereby agree to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice and this RSU Agreement.

11. **Entire Agreement; Enforcement of Rights**. This RSU Agreement, the Plan and the Notice constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning the purchase of the Shares hereunder are superseded. No modification of or amendment to this RSU Agreement, nor any waiver of any rights under this RSU Agreement, shall be effective unless in writing and signed by the parties to this RSU Agreement. The failure by either party to enforce any rights under this RSU Agreement shall not be construed as a waiver of any rights of such party.

12. **Compliance with Laws and Regulations**. The issuance of Shares will be subject to and conditioned upon compliance by the Company and you with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Common Stock may be listed or quoted at the time of such issuance or transfer, which compliance the Company shall, in its absolute discretion, deem necessary or advisable. You understand that the Company is under no obligation to register or qualify the Common Stock with any state, federal or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the Shares. Further, you agree that the Company shall have unilateral authority to amend the Plan and this RSU Agreement without your consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares. Finally, the Shares issued pursuant to this RSU Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

13. **No Advice Regarding Grant**. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

14. **Governing Law; Venue**. This RSU Agreement, all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law. For purposes of litigating any dispute that may arise directly or indirectly from the Plan, the Notice and this RSU Agreement, the parties hereby submit and consent to litigation in the exclusive jurisdiction of the State of California and agree that any such litigation shall be conducted only in the courts of California in San Diego County, California or the federal courts of the United States for the Southern District of California and no other courts.

15. **Severability**. If one or more provisions of this RSU Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this RSU Agreement, (ii) the balance of

this RSU Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of this RSU Agreement shall be enforceable in accordance with its terms.

16. No Rights as Employee, Director or Consultant. Nothing in this RSU Agreement shall affect in any manner whatsoever the right or power of the Company, or a Parent or Subsidiary of the Company, to terminate your Service, for any reason, with or without Cause.

17. Consent to Electronic Delivery and Acceptance of All Plan Documents and Disclosures. By your acceptance of this award of RSUs, you consent to the electronic delivery of the Notice, this RSU Agreement, the Plan, account statements, Plan prospectuses required by the SEC, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its stockholders (including, without limitation, annual reports and proxy statements) or other communications or information related to the RSUs. Electronic delivery may include the delivery of a link to a Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. You acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost if you contact the Company by telephone, through a postal service or electronic mail at [insert email]. You further acknowledge that you will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, you understand that you must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. You agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company. Also, you understand that your consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if you have provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail at [insert email]. Finally, you understand that you are not required to consent to electronic delivery.

18. Insider Trading Restrictions/Market Abuse Laws. You acknowledge that, depending on your country, you may be subject to insider trading restrictions and/or market abuse laws, which may affect your ability to acquire or sell the Shares or rights to Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you are advised to speak to your personal advisor on this matter.

19. Language. If you have received this RSU Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

20. Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan, on the RSUs and on any Shares acquired under

the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

21. **Waiver**. You acknowledge that a waiver by the Company of breach of any provision of this RSU Agreement shall not operate or be construed as a waiver of any other provision of this RSU Agreement, or of any subsequent breach by you or any other Participant.

22. **Code Section 409A.** To the extent applicable, this RSU Agreement shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder ("***Section 409A***"), including without limitation any such regulations or other guidance that may be issued after the Date of Grant. Notwithstanding any other provision of the Plan, the Notice or this RSU Agreement, if at any time the Committee determines that the RSUs (or any portion thereof) may be subject to Section 409A, the Committee shall have the right in its sole discretion (without any obligation to do so or to indemnify you or any other person for failure to do so) to adopt such amendments to the Plan, the Notice or this RSU Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Committee determines are necessary or appropriate for the RSUs to be exempt from the application of Section 409A or to comply with the requirements of Section 409A. For purposes of this RSU Agreement, a termination of employment or service will be determined consistent with the rules relating to a "separation from service" as defined in Section 409A. Notwithstanding anything else provided herein, to the extent you are deemed at the time of such termination of employment or service to be a "specified employee" under Section 409A, then such payment shall not be made or commence until the earlier of (i) the first business day following the expiration of the six-month period measured from your separation from service from the Company or (ii) the date of your death following such a separation from service; provided, however, that such deferral shall only be effected to the extent required to avoid adverse tax treatment to you including, without limitation, the additional tax for which you would otherwise be liable under Section 409A(a)(1)(B) in the absence of such a deferral. Payments pursuant to this section are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

23. **Award Subject to Company Clawback or Recoupment**. The RSUs shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of your employment or other Service that is applicable to executive officers, Employees, Directors or other service providers of the Company, and in addition to any other remedies available under such policy and applicable law may require the cancellation of your RSUs (whether vested or unvested) and the recoupment of any gains realized with respect to your RSUs.

BY ACCEPTING THIS AWARD OF RSUS, YOU AGREE TO ALL OF THE TERMS AND CONDITIONS DESCRIBED ABOVE AND IN THE PLAN.

Exhibit 10.33

NOTICE OF RESTRICTED STOCK UNIT AWARD
(WITH SHARE AND CASH SETTLEMENT)
OBALON THERAPEUTICS, INC. 2016 EQUITY INCENTIVE PLAN

Unless otherwise defined herein, the terms defined in the Obalon Therapeutics, Inc. (the "***Company***") 2016 Equity Incentive Plan (the "***Plan***") shall have the same meanings in this Notice of Restricted Stock Unit Award (the "***Notice***") and the attached Award Agreement (Restricted Stock Unit Agreement, including any special terms and conditions for your country set forth in the appendix attached thereto (collectively, the "***RSU Agreement***")). You ("***you***") have been granted an award of Restricted Stock Units ("***RSUs***") under the Plan subject to the terms and conditions of the Plan, this Notice and the attached RSU Agreement.

Name:

Address:

Number of RSUs:

Date of Grant:

You acknowledge that the vesting of the RSUs pursuant to this Notice is earned only by continued Service through the Vesting Date (as defined in Exhibit A). For the avoidance of doubt, any termination of Service (whether voluntary or involuntary) shall mean your RSUs under this RSU Agreement shall be automatically cancelled and forfeited by you for no consideration therefor. By accepting this award, you and the Company agree that this award is granted under and governed by the terms and conditions of the Plan, this Notice and the RSU Agreement. By accepting this award of RSUs, you consent to the electronic delivery and acceptance as further set forth in the RSU Agreement.

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PARTICIPANT	**OBALON THERAPEUTICS INC.**
Signature:	By:
Print Name:	Its:

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RESTRICTED STOCK UNIT AGREEMENT

OBALON THERAPEUTICS, INC.

2016 EQUITY INCENTIVE PLAN

You have been granted Restricted Stock Units ("***RSUs***") by Obalon Therapeutics, Inc. (the "***Company***") subject to the terms, restrictions and conditions of the Plan, the Notice of Restricted Stock Unit Award (the "***Notice***") and this Restricted Stock Unit Agreement, including any special terms and conditions for your country set forth in the appendix attached hereto (the "***Appendix***") (collectively, this "***RSU Agreement***").

1. **Nature of Grant**. In accepting this award of RSUs, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the RSUs is voluntary and occasional and does not create any contractual or other right to receive future awards of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past;

(c) all decisions with respect to future RSUs or other grants, if any, will be at the sole discretion of the Company;

(d) you are voluntarily participating in the Plan;

(e) the RSUs and the Shares subject to the RSUs, and the income and value of the same, are not intended to replace any pension rights or compensation;

(f) the RSUs and the Shares subject to the RSUs, and the income and value of the same, are not part of normal or expected compensation for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) unless otherwise agreed with the Company, the RSUs and any Shares acquired under the Plan, and the income and value of the same, are not granted as consideration for, or in connection with, any service you may provide as a director of the Company, or a Parent or Subsidiary of the Company;

(h) the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the RSUs resulting from the termination of your Service (for any reason whatsoever whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are providing Service or the terms of your employment or service agreement, if any), and in consideration of the grant of the RSUs to which you are otherwise not entitled, you irrevocably agree never to institute any claim against the Company, the Employer (as defined below), or any other Parent or Subsidiary of the Company, waive your ability, if any, to bring any such claim, and release the Company, the Employer and its Parent or Subsidiaries from any such

claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, you shall be deemed irrevocably to have agreed not to pursue such claim and agree to execute any and all documents necessary to request dismissal or withdrawal of such claim; and

(j) the following provisions apply only if you are providing Service outside the United States: (i) the RSUs and the Shares subject to the RSUs, and the income and value of same, are not part of normal or expected compensation or salary for any purpose; and (ii) neither the Company, the Employer nor any Parent or Subsidiary of the Company shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the RSUs or the subsequent sale of any Shares acquired upon settlement.

2. **Settlement**. Settlement of RSUs shall be made no later than March 15 of the year following the year in which the Vesting Date occurs. Settlement of RSUs shall be in Shares or cash; provided, however, that if, as of the applicable settlement date, insufficient Shares remain available under the Plan to cover settlement of any or all of the RSUs for which payment is required, as determined by the Committee, such RSUs shall be paid in cash in an amount equal to the Fair Market Value as of the settlement date of the Shares otherwise distributable on such settlement date. Settlement means the delivery to you of the Shares vested under the RSUs and/or a cash payment with respect to such vested RSUs. Fractional Shares will not be issued.

3. **No Stockholder Rights**. Prior to the issuance of Shares in settlement of vested RSUs, if any, you shall have no ownership of any Shares underlying the RSUs and shall have no right to dividends or to vote such Shares.

4. **Dividend Equivalents**. Dividends, if any (whether in cash or Shares), shall not be credited to you.

5. **No Transfer**. RSUs may not be sold, assigned, transferred, pledged, hypothecated, or otherwise disposed of in any manner other than by will or by the laws of descent or distribution or court order or unless otherwise permitted by the Committee on a case-by-case basis.

6. **Termination**. If your Service terminates for any reason, all unvested RSUs shall be forfeited to the Company forthwith, and all rights you have to such RSUs shall immediately terminate, without payment of any consideration to you. For purposes of this award of RSUs, your Service will be considered terminated as of the date you are no longer providing Service (regardless of the reason for such termination and whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are employed or the terms of your employment or service agreement, if any) and will not be extended by any notice period mandated under local employment laws (*e.g.*, Service would not include a period of "garden leave" or similar period). In case of any dispute as to whether your termination of Service has occurred, the Committee shall have sole discretion to determine whether such termination has occurred (including whether you may still be considered to be providing Services while on a leave of absence) and the effective date of such termination.

7. **Tax Consequences**. You acknowledge that there will be certain consequences with regard to income tax, national or social insurance contributions, payroll tax, fringe benefits tax, payment on account or other tax-related items ("***Tax-Related Items***") upon settlement of the RSUs or disposition of the Shares, if any, received in connection therewith, and you should consult a tax adviser regarding your tax obligations prior to such settlement or disposition in the jurisdiction where you are subject to tax.

8. **Responsibility for Taxes**. Regardless of any action the Company or, if different, your actual employer (the "***Employer***") takes with respect to any or all Tax-Related Items withholding or required deductions, you acknowledge that the ultimate liability for all Tax-Related Items legally due by you is and

remains your responsibility and that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the award, including the grant, vesting or settlement of the RSUs, the subsequent sale of Shares acquired pursuant to such settlement and the receipt of any dividends; and (2) do not commit to structure the terms of the award or any aspect of the RSUs to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You acknowledge that if you are subject to Tax-Related Items in more than one jurisdiction, the Company and/or the Employer may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to the settlement of your RSUs, you shall pay or make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Items withholding and payment on account obligations of the Company and/or the Employer. In this regard, you authorize the Company and/or the Employer, and their respective agents, at their discretion, to withhold all applicable Tax-Related Items legally payable by you from your wages or other cash compensation paid to you by the Company and/or the Employer. These arrangements may also include, if permissible under local law, (a) withholding Shares that otherwise would be issued to you when your RSUs are settled, provided that the Company only withholds the amount of Shares necessary to satisfy the minimum statutory withholding amount, (b) having the Company withhold taxes from the proceeds of the sale of the Shares, either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization), (c) payment by you of an amount equal to the Tax-Related Items directly by cash, cheque, wire transfer, bank draft or money order payable to the Company, or (d) any other arrangement approved by the Company; in each case in compliance with such rules as may be established by the Committee and in compliance with the Company's Insider Trading Policy and 10b5-1 Trading Plan Policy, if applicable; provided, however, that if you are a Section 16 officer of the Company under the Exchange Act, then alternative (c) shall be the method of withholding. The Fair Market Value of these Shares, determined as of the effective date when taxes otherwise would have been withheld in cash, will be applied as a credit against the Tax-Related Items.

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Shares equivalent and/or cash settlement of such RSUs. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, you are deemed to have been issued the full number of Shares subject to the vested RSUs, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax-Related Items.

Finally, you agree to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold as a result of your participation in the Plan or the vesting and settlement of the RSUs that cannot be satisfied by the means previously described. You acknowledge that the Company has no obligation to deliver any payment with respect to the RSUs to you until you have satisfied the obligations in connection with the Tax-Related Items as described in this Section.

9. **Data Privacy**. *You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this RSU Agreement and any other RSU grant materials by and among, as applicable, the Company, the Employer and any other Parent or Subsidiaries, for the exclusive purpose of implementing, administering and managing your participation in the Plan.*

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of stock or directorships held

*in the Company, details of all RSUs or any other entitlement to shares of stock awarded, canceled, exercised, vested, unvested or outstanding in your favor ("**Data**"), for the exclusive purpose of implementing, administering and managing the Plan.*

You understand that Data will be transferred to the stock plan service provider as may be designated by the Company from time to time, which is assisting the Company with the implementation, administration and management of the Plan. You understand that the recipients of Data may be located in the United States or elsewhere, and that the recipients' country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that if you reside outside the United States, you may request a list with the names and addresses of any potential recipients of Data by contacting your local human resources representative. You authorize the Company, the designated broker and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer Data, in electronic or other form, for the sole purpose of implementing, administering and managing your participation in the Plan. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that if you reside outside the United States, you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. Further, you understand that you are providing the consents herein on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your employment status or service and career with the Employer will not be adversely affected. The only adverse consequence of refusing or withdrawing your consent is that the Company would not be able to grant you RSUs or other equity awards or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

10. **Acknowledgement**. The Company and you agree that the RSUs are granted under and governed by the Notice, this RSU Agreement and the provisions of the Plan. You: (i) acknowledge receipt of a copy of the Plan prospectus, (ii) represent that you have carefully read and are familiar with the provisions in the grant documents, and (iii) hereby accept the RSUs subject to all of the terms and conditions set forth in this RSU Agreement and those set forth in the Notice. You hereby agree to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice and this RSU Agreement.

11. **Entire Agreement; Enforcement of Rights**. This RSU Agreement, the Plan and the Notice constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning the purchase of the Shares hereunder are superseded. No modification of or amendment to this RSU Agreement, nor any waiver of any rights under this RSU Agreement, shall be effective unless in writing and signed by the parties to this RSU Agreement. The failure by either party to enforce any rights under this RSU Agreement shall not be construed as a waiver of any rights of such party.

12. **Compliance with Laws and Regulations**. The issuance of Shares in settlement of your RSUs, if any, will be subject to and conditioned upon compliance by the Company and you with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Common Stock may be listed or quoted at the time of such issuance or transfer, which compliance the Company shall, in its absolute discretion, deem necessary or advisable. You understand that the Company is under no obligation to register or qualify the Common Stock with any state, federal or foreign securities commission or to seek approval or clearance from any

governmental authority for the issuance or sale of the Shares. Further, you agree that the Company shall have unilateral authority to amend the Plan and this RSU Agreement without your consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares. Finally, the Shares issued pursuant to this RSU Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

13. **No Advice Regarding Grant**. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of any underlying Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

14. **Governing Law; Venue**. This RSU Agreement, all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law. For purposes of litigating any dispute that may arise directly or indirectly from the Plan, the Notice and this RSU Agreement, the parties hereby submit and consent to litigation in the exclusive jurisdiction of the State of California and agree that any such litigation shall be conducted only in the courts of California in San Diego County, California or the federal courts of the United States for the Southern District of California and no other courts.

15. **Severability**. If one or more provisions of this RSU Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this RSU Agreement, (ii) the balance of this RSU Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of this RSU Agreement shall be enforceable in accordance with its terms.

16. **No Rights as Employee, Director or Consultant**. Nothing in this RSU Agreement shall affect in any manner whatsoever the right or power of the Company, or a Parent or Subsidiary of the Company, to terminate your Service, for any reason, with or without Cause.

17. **Consent to Electronic Delivery and Acceptance of All Plan Documents and Disclosures**. By your acceptance of this award of RSUs, you consent to the electronic delivery of the Notice, this RSU Agreement, the Plan, account statements, Plan prospectuses required by the SEC, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its stockholders (including, without limitation, annual reports and proxy statements) or other communications or information related to the RSUs. Electronic delivery may include the delivery of a link to a Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. You acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost if you contact the Company by telephone, through a postal service or electronic mail at [email]. You further acknowledge that you will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, you understand that you must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. You agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company. Also, you understand that your consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if you have provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail at [email]. Finally, you understand that you are not required to consent to electronic delivery.

18. **Insider Trading Restrictions/Market Abuse Laws**. You acknowledge that, depending on your country, you may be subject to insider trading restrictions and/or market abuse laws, which may affect

your ability to acquire or sell the Shares or rights to Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you are advised to speak to your personal advisor on this matter.

19. **Language**. If you have received this RSU Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

20. **Appendix**. Notwithstanding any provisions in this Restricted Stock Unit Agreement, this award of RSUs shall be subject to any special terms and conditions set forth in any Appendix hereto for your country. Moreover, if you relocate to one of the countries included in the Appendix, the special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this RSU Agreement.

21. **Imposition of Other Requirements**. The Company reserves the right to impose other requirements on your participation in the Plan, on the RSUs and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

22. **Waiver**. You acknowledge that a waiver by the Company of breach of any provision of this RSU Agreement shall not operate or be construed as a waiver of any other provision of this RSU Agreement, or of any subsequent breach by you or any other Participant.

23. **Code Section 409A**. For purposes of this RSU Agreement, a termination of employment will be determined consistent with the rules relating to a "separation from service" as defined in Section 409A of the Code and the regulations thereunder ("***Section 409A***"). Notwithstanding anything else provided herein, to the extent any payments provided under this RSU Agreement in connection with your termination of employment constitute deferred compensation subject to Section 409A, and you are deemed at the time of such termination of employment to be a "specified employee" under Section 409A, then such payment shall not be made or commence until the earlier of (i) the expiration of the six-month period measured from your separation from service from the Company or (ii) the date of your death following such a separation from service; provided, however, that such deferral shall only be effected to the extent required to avoid adverse tax treatment to you including, without limitation, the additional tax for which you would otherwise be liable under Section 409A(a)(1)(B) in the absence of such a deferral. To the extent any payment under this RSU Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. Payments pursuant to this section are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

24. **Award Subject to Company Clawback or Recoupment**. The RSUs shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of your employment or other Service that is applicable to executive officers, Employees, Directors or other service providers of the Company, and in addition to any other remedies available under such policy and applicable law may require the cancellation of your RSUs (whether vested or unvested) and the recoupment of any gains realized with respect to your RSUs.

BY ACCEPTING THIS AWARD OF RSUS, YOU AGREE TO ALL OF THE TERMS AND CONDITIONS DESCRIBED ABOVE AND IN THE PLAN.

EXHIBIT A

Vesting:

Subject to your continuous Service, your RSUs shall vest on the Vesting Date based on the Final Share Price (as defined below) as of such date:

Final Share Price per Share	**Percentage of RSUs that Vest**
< $11.00	0%
≥ $11.00 but < $16.00	50% or 40%
≥ $16.00 but < $21.00	70% or 60%
≥ $21.00	100%

Notwithstanding the foregoing, unless otherwise determined by the Committee, in the event that the Net Aggregate Evergreen Increase (as defined below) is less than the aggregate number of RSUs that vest pursuant to this Program (as defined below), then the aggregate number of RSUs that are eligible to vest pursuant to this Program (including this Award) shall be reduced pro rata such that the sum of all RSUs that vest under this Program (including this Award) shall equal the Net Aggregate Evergreen Increase and the remaining RSUs shall be automatically cancelled and forfeited on the Vesting Date, and the Participant's rights in any such RSUs shall lapse and expire.

Any RSUs that do not vest for failure to achieve the applicable Final Share Price goal (in whole or in part) shall be automatically cancelled and forfeited on the Vesting Date, and the Participant's rights in any such RSUs shall lapse and expire.

Settlement:

The Shares shall be settled in Shares and/or in cash, as determined by the Committee in its sole discretion.

Adjustments:

You acknowledge that the Final Share Price goal, the RSUs, and the Shares subject to the RSUs are subject to adjustment in certain events as provided in the Plan.

Definitions:

"***Corporate Transaction***" shall have the meaning set forth in the Plan, but shall not include subclause (e) (regarding a Board turnover).

"***Final Share Price***" shall mean the Common Stock's 40 trading-day trailing average over the period ending on (and including) December 31, 2022; *provided, however,* that if a Corporate Transaction occurs prior to or on December 31, 2022, the Final Share Price shall mean the price per Share paid by the acquiror in the Change in Control transaction or, to the extent that the consideration in the Corporate Transaction is paid in stock of the acquiror or its affiliate, then, unless otherwise determined by the Committee (including in

connection with valuing any shares that are not publicly traded), the Final Share Price shall mean the value of the consideration paid per Share based on the average of the closing trading prices of a share of such acquiror stock on the principal exchange on which such shares are then traded for each trading day during the five consecutive trading days ending on and including the date on which a Corporate Transaction occurs.

"***Net Aggregate Evergreen Increase***" shall mean the difference between (i) the aggregate number of Shares that become available for issuance pursuant to Section 2.4 of the Plan on January 1 of each of 2020, 2021, 2022 and 2023 minus (ii) the aggregate number of Shares underlying equity awards granted under the Plan, other than pursuant to this Program, which have an effective grant date that occurs during the Performance Period (but excluding for this purpose Shares subject to such awards that again become available for grant under the Plan pursuant to Section 2.2(b) or (c) of the Plan)).

"***Performance Period***" means the period beginning on January 1, 2020 and ending on the Vesting Date.

"***Program***" shall mean this Award, together with all other Awards granted pursuant to this Agreement under the Plan.

"***Vesting Date***" shall mean the earlier of: (i) December 31, 2022 or (ii) the consummation of a Corporate Transaction.

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

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, and 333-236062) 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 sheets of Obalon Therapeutics, Inc. as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes, which report appears in the December 31, 2019 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 an accumulated deficit, 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. Our report also refers to the adoption of Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, as amended.

/s/ KPMG LLP

San Diego, California
February 27, 2020

Exhibit 31.1

Obalon Therapeutics, Inc.
Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, William Plovanic, 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.

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: February 27, 2020

/s/ William Plovanic

William Plovanic
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.

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: February 27, 2020

/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, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), William Plovanic, 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: February 27, 2020

/s/ William Plovanic	/s/ Nooshin Hussainy
William Plovanic	Nooshin Hussainy
President and Chief Executive Officer (Principal Executive Officer)	Chief Financial 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.