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, 2016
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)**

(760) 795-6558
(Registrant's Telephone Number, Including Area Code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value per share	**The Nasdaq Stock Market LLC**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer	☐		Accelerated filer	☐
Non-accelerated filer	☒	(Do not check if a smaller reporting company)	Smaller reporting company	☐

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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The registrant's common stock began trading on The NASDAQ Global Market on October 6, 2016

Total shares of common stock outstanding as of the close of business on February 17, 2017 was 16,773,205 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 2017 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," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan" "expect," 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 "Risk factors" and elsewhere in this Annual Report. Moreover, we operate in a 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 assure 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 obese and overweight people by facilitating weight loss. Our initial 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 obese patients. We designed the Obalon balloon system to address many of the limitations of prior devices intended to treat weight loss, including traditional saline-filled intragastric balloons. 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 attractive economics for patients and physicians.

In September 2016, we received premarket approval, or PMA, from the FDA, and commenced U.S. commercialization in January 2017. The Obalon balloon system is FDA approved for temporary use to facilitate weight loss in obese adults with a body mass index, or 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. The Obalon balloon system has the potential to provide patients and physicians with a cost-effective, reversible and repeatable weight loss solution in an outpatient setting, without altering patient anatomy or requiring surgery. As of December 31, 2016, we had sold over 26,000 of our earlier generation Obalon balloon systems for commercial use outside the United States.

We received PMA approval for our Obalon balloon system based on the results of our U.S. pivotal clinical trial, referred to as the SMART trial. The SMART trial was a prospective, double-blinded, multi-center, randomized (1:1), parallel-group, active sham-controlled trial involving 387 patients, which demonstrated that patients in the Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham-control group, while at the same time maintaining a low rate of serious adverse device events, or SADEs. In the SMART trial, the Obalon balloon system also demonstrated a strong safety profile, showed statistically significant differences in metabolic profiles and demonstrated that patients were able to maintain most of their weight loss for at least six months following the removal of the balloons.

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 86 million adults in the United States were obese, defined as a BMI of 30 or greater (calculated as weight in kilograms divided by height in meters squared), of which approximately 17.6 million were considered extremely obese with a BMI of 40 or greater, and an additional 75 million adults in the United States were overweight, defined as a BMI between 25 and 29. Research sponsored by the Centers for Disease Control and Prevention, or CDC, suggests that if current obesity rates persist, more than half of the U.S. population will be obese by 2030. Similarly, obesity is also a significant health problem outside of the United States. The number of obese adults worldwide has more than doubled since 1980, and the World Health Organization estimates that more than 600 million adults were obese and more than 1.9 billion were overweight in 2014.

The CDC has identified obesity as a leading cause of preventable death in the United States. Obesity-related disorders, known as comorbidities, include Type 2 diabetes, hypertension, stroke and certain cancers as well as psychological disorders such as anxiety, depression and insomnia. 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 approximately $210 billion in 2008. Furthermore, the annual global economic impact of obesity is 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 obese and overweight patients begin with lifestyle modification, such as diet and exercise. If this alternative 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 such products only treat the symptoms and not the underlying disease. They are also not indicated for obese patients.

Lifestyle modification

Lifestyle modification, which includes diet, exercise and behavior modification, is usually prescribed as an initial treatment for an obese or overweight patient and is typically prescribed in all obesity management approaches. However, lifestyle modification alone has generally been ineffective in producing sustainable weight loss in obese patients 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 obese patients 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 two most common forms of bariatric surgery, gastric bypass and gastric banding, 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 traditional saline-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, saline-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. Other approved traditional saline-filled intragastric balloons in the United States are the ReShape Duo Balloon and the ORBERA Balloon. While generally effective in delivering weight loss, these traditional saline-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 saline-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 SADE. As of December 2016, we had sold over 26,000 units of our earlier generation Obalon balloon systems in international markets with a minimal number of SADEs reported to us, none of which were required to be reported to the applicable foreign regulatory authorities. Our investigations determined that all of the international SADEs occurred in patients where the device was not used in accordance with approved labeling.
- ***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 saline-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.
- ***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 ten 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.
- ***Attractive economics for patients and physicians.*** By eliminating the need for an endoscopic delivery procedure, anesthesia and use of a special endoscopy suite, we believe our Obalon balloon system has the potential to reduce physician costs and allow more time to perform additional procedures. Furthermore, the Obalon balloon's tolerability profile may reduce the need for ongoing patient management. We believe patients will benefit from lower treatment costs, no post-placement recovery period and a quick return to daily activities.

OUR STRATEGY

Our objective is to be the leading provider of medical devices for the non-surgical treatment of obese and overweight individuals. The key elements of our strategy are to:

- ***Drive product adoption by working with key thought leaders in bariatrics, gastroenterology and plastic surgery.*** We are initially focused on direct sales to the leading bariatric surgeons, gastroenterologists, and plastic surgeons in the United States. We estimate that there are approximately 3,500 bariatric surgery centers in the United States, and we believe the leading 700 centers provide an opportunity to effectively access obese patients using an efficiently-sized sales force. In addition, there are over 15,000 gastroenterologists, many of which are expanding their practices to include weight loss treatments, and 1,900 aesthetically focused plastic surgeons. We believe adoption of our technology by these thought leaders will accelerate broader adoption of the Obalon balloon system in each physician specialty area.
- ***Partner with physicians to create consumer awareness and drive patients into the channel.*** Our initial strategy is to establish marketing and support programs with physicians to create patient awareness and demand for the Obalon balloon system. We support these physicians with best practices and tools to treat qualified patients already in the channel and through local outreach to attract new patients to the practice. We also provide physicians with the clinical training to utilize our Obalon balloon system, as well as the practice development support to manage their practices as self-pay centers. In addition, we believe we can address an even larger patient population by creating a recognizable brand name through a direct-to-patient campaign designed to differentiate the Obalon balloon system using targeted, cost effective digital and social media platforms, and media outreach through public relations efforts.
- ***Continue to develop innovative products to facilitate market penetration.*** We plan to leverage our proprietary product technology and research and development expertise to develop products for weight loss that improve clinical outcomes, increase ease of use and reduce cost. For example, we plan to seek supplemental approval for improvements to our Obalon balloon system, including a new, automated, easier-to-use inflation system. Other products currently in our development pipeline include a navigation system that would reduce the need for imaging at every placement, a balloon with a treatment period of longer than six months and a self-deflating and self-passing balloon that could eliminate the need for endoscopic balloon removal.
- ***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 our products in-house 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 cost-efficiently and produce higher quality products than if we outsourced manufacturing. We believe we have the ability to increase our manufacturing scale 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 Obalon balloon system was designed to overcome the historical limitations of traditional saline-filled intragastric balloons and nonsurgical treatments for weight loss. We have developed the individual components of the Obalon balloon system to collectively improve clinical outcomes, increase ease of use and reduce cost.

The Obalon balloon system

The main components of the Obalon balloon system are: a swallowable capsule that contains the balloon attached to a microcatheter, a hand-held inflation system and a pre-filled can of our proprietary mix 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

Our hand-held inflation system, the EzFill inflation system, is a reusable device that delivers our proprietary mixture of gas to consistently inflate the Obalon balloon to the standardized volume and pressure. The inflation system is equipped with pre-pulse, a confirmation system that provides pressure feedback measurements to confirm that the Obalon balloon is both properly placed and able to be correctly inflated in the stomach.

Proprietary gas

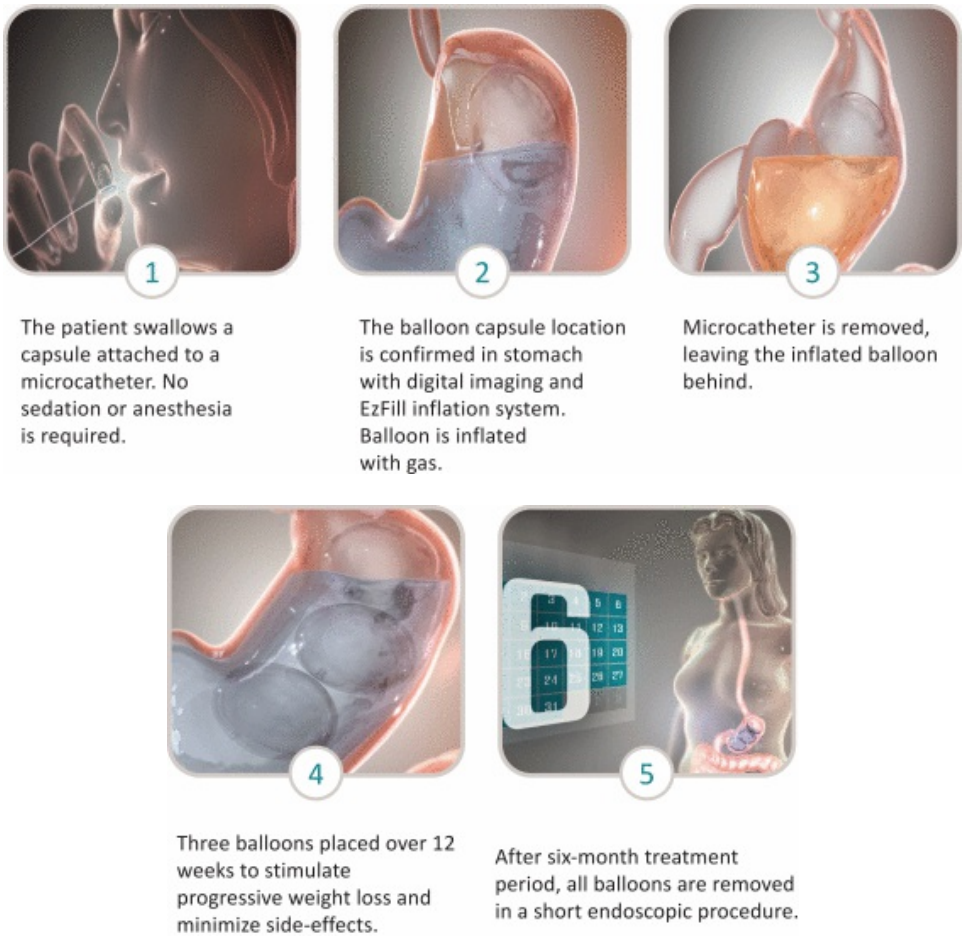
The Obalon balloon is inflated with our proprietary mix of gas, which, in combination with the permeability of the balloon film and the stomach gases, enables the balloon to remain inflated for the full six-month treatment period.

The Obalon balloon treatment

Placement of the Obalon balloon typically occurs in less than ten 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 with digital imaging. The microcatheter, which is attached to the Obalon balloon, is then connected to our EzFill inflation system. The EzFill inflation system 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 can of gas is inserted into the EzFill 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 returns 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 750cc.

All of the balloons are removed in a single procedure six months after the placement of the initial balloon. Removal of the Obalon balloon typically requires approximately 15 minutes. The balloons are removed endoscopically under light conscious sedation, using standard commercially-available endoscopy tools.

The following pictures depict the treatment steps of the Obalon balloon system:



Product pipeline

We have a robust pipeline of new products and product improvements for weight loss intended to improve clinical outcomes, increase ease of use and reduce cost.

Next generation balloon capsule

We have developed a next generation HydroxyPropylMethylCellulose, or HPMC, Obalon balloon capsule that is fully vegetable-derived and is intended to eliminate potential cultural or religious concerns with animal-derived gelatin capsules. We submitted a PMA supplement for the HPMC Obalon balloon capsule in the United States in November 2016.

Next generation inflation system

Our next generation inflation system, the Obalon Touch inflation system (formerly known as the EzPz inflation system), is designed to be automated, simpler to operate and to provide more reliable Obalon balloon placements. Due to the enhancements, we are currently updating our Certificat de Conformité, or CE, mark registrations as well as applying for a modification to the existing EzPz approval in Brazil and select Middle East markets. In the United States, we believe the Obalon Touch inflation system will require a PMA Supplement for approval.

Navigation

We are developing a balloon and navigation system for balloon placements that would reduce the need for digital imaging at each placement. We believe this navigation system has the potential to reduce the cost and logistics related to confirmatory digital imaging during the Obalon balloon placement, which could enable physician practices to treat higher volumes of patients and increase the number of physicians and sites offering the Obalon balloon system. The navigation system consists of hardware, software and a display to be used in conjunction with the current Obalon balloon. We have completed two feasibility studies for proof-of-concept and intend to conduct further clinical studies with this navigation system.

Longer-term duration balloon system

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 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 complete more rigorous engineering testing and submit for approval to conduct human trials to understand if longer balloon treatment may address higher BMI patients or those desiring a longer weight loss treatment.

Deflateable-passable balloon system

We have a balloon system in development that is intended to self-deflate at the end of a specified treatment period and then pass naturally through the digestive system to be excreted as waste, thereby potentially eliminating the need for endoscopy and creating a procedureless balloon treatment. However, it is of paramount importance to patient safety that such a balloon would pass with an extremely high level of reliability and not create a blockage of the intestines, which could require surgery and cause significant patient injury or death. We have conducted initial engineering and animal testing successfully on self-deflating and self-passing balloons, and we believe we have developed novel technology with a strong intellectual property portfolio. We intend to continue development and testing, and, if the results of our studies warrant, move toward human clinical trials in support of regulatory approvals.

Research and development

As of December 31, 2016, we had 11 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, 2016, 2015 and 2014 were $9.9 million, $13.0 million and $5.8 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 655 patients as of December 31, 2016. 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 SMART trial met its primary weight loss endpoints, demonstrated a strong safety profile, 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. The patients ranged in age from 22 to 64 years and had a BMI range of 30 to 40. The patients enrolled were required to have previously attempted to lose weight unsuccessfully through a change in diet and could not use weight loss medications or undergo gastric surgery for the duration of the trial. 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 total body loss, or 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.

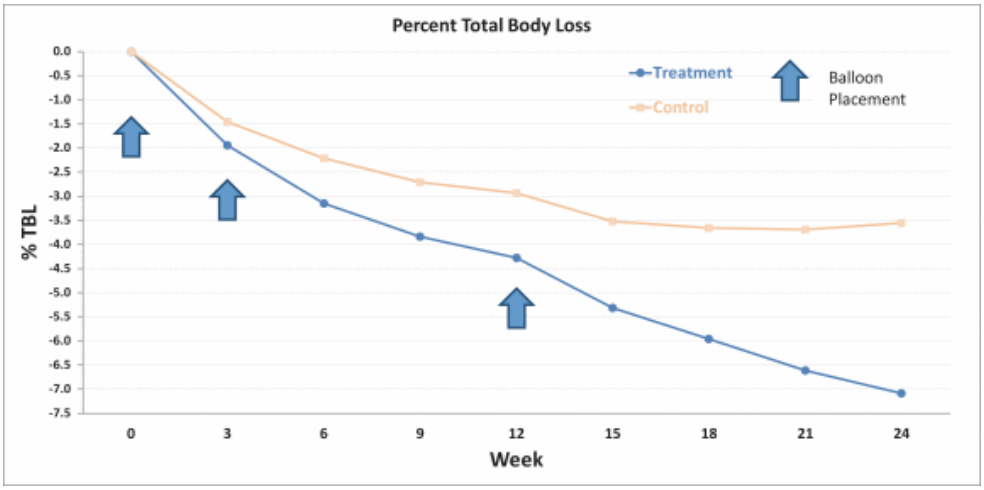
Main Analysis of -5% TBL Responder Rate	Estimate
Obalon Treatment Group—Per Protocol Cohort*	120 / 185 (64.9%)
Sham-Control Group	58 / 181 (32.0%)
Difference (Treatment less Control)	32.8%

* 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.

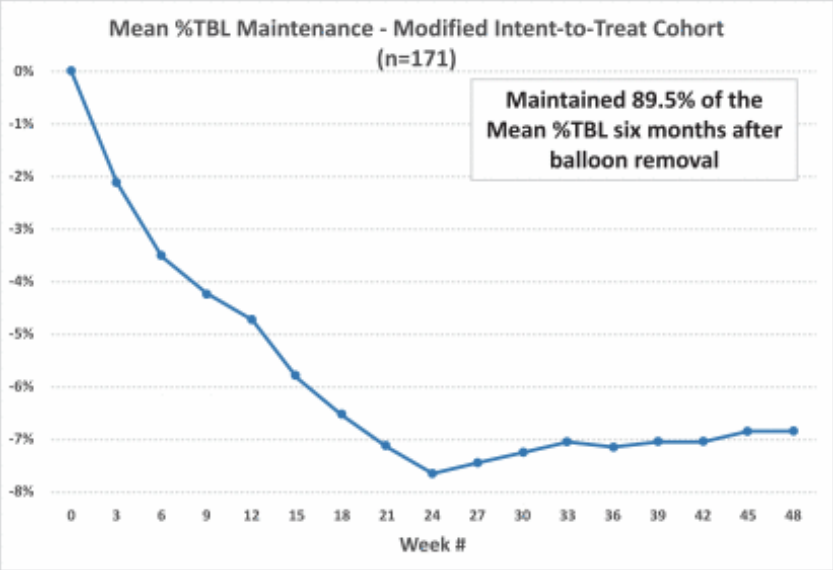


In addition, nearly all patients in the Obalon treatment group, including patients in the bottom 25% of the group, achieved TBL, EWL and weight loss and a reduction in BMI. The table below summarizes the mean, the average of the top 25% of the results, the average of the bottom 25% of the results and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



Safety

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 safety experience

As of December 2016, we had sold over 26,000 units of our earlier generation Obalon balloon systems in international markets. In our commercial experience, nine serious adverse events have been reported to us, of which six related to balloon deflations resulting in migration and three related to an esophageal laceration or rupture. We investigated each of these events and determined that all nine of these events occurred in patients where the device was not used in accordance with approved labeling. None of these events were required to be reported to the applicable foreign regulatory authorities. We have never had a case of pancreatitis or spontaneous hyperinflation reported in almost five years of international commercialization.

SMARTCAR trial

In April 2016, we received an Investigational Device Exemption, or IDE, approval from the FDA to conduct a single arm clinical study, which we named SMARTCAR, to evaluate the safety and efficacy profile of our new HPMC vegetable-derived capsule and the EzPz inflation system (currently Obalon Touch inflation system). We enrolled an initial 25 patients for the trial at three clinical sites in the United States. Twenty-one patients met the SMART Pivotal Trial Per Protocol requirement of having at least two balloons placed for 18 weeks or more and demonstrated weight loss of 11.3% TBL and 23.2 pounds. There were no serious adverse events reported.

Post-approval study

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 200 patients have completed the study. We are currently working with FDA to finalize the data collection requirements for the study.

Commercial-Use Patient Registry

In order to most closely monitor the safety, efficacy and quality of the Obalon balloon system real time in actual commercial use, we have created an online clinical performance database, or registry. All physicians and sites using the Obalon balloon system have access to the registry to enter their patient data and to compare their performance to national or 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. Obalon may use knowledge gained from analyzing the data from the registry for scientific publications, for improving clinical practices, for developing new and improved products, for commercial purposes or to provide information to regulatory bodies.

SALES AND MARKETING

Our primary sales efforts are expected to be conducted in the United States, with some sales generated through distributors in select international markets. We sell in the United States through a direct sales organization consisting of regional sales directors, executive account managers and product specialists. Our sales team encompasses three key disciplines that we believe are necessary to create and grow the market for our Obalon balloon system in the United States: sales conversion, practice development and clinical training and application. In select international markets, we plan to utilize distributors.

We currently have an agreement to sell to Bader Sultan & Bros. Co. W.L.L., or Bader, as the sole distributor of our Obalon balloon system in the Middle East. Our agreement with Bader restricts Bader's ability to sell competing products and requires Bader to purchase a certain number of products from us monthly based on annual forecasts that we provide to Bader. If Bader does not resell the minimum purchase quantity specified in the contract by the applicable date, then we have the right, in our sole discretion, to sell to other distributors in the Middle East or terminate our agreement with Bader. The agreement can be terminated by us immediately upon certain breaches by Bader, or by either Bader or us for uncured material breach of the agreement. We have discontinued sales of our prior generation product in the Middle East and do not plan to begin selling in the Middle East again until our next generation inflation system is approved. We are currently working closely with Bader to determine the best timing and strategy for launch of the current generation Obalon balloon system with the next generation inflation system in the Middle East.

Our initial U.S. marketing efforts are focused on differentiating the benefits of our technology, leveraging the strong clinical outcome from our SMART trial, working with key thought leaders in bariatrics, gastroenterology, and plastic surgery, and partnering with physicians to create consumer awareness and drive patients into the channel. We also intend to provide physicians with the clinical training to utilize our Obalon balloon system, as well as the practice development support to manage their practices as self-pay centers.

In an effort to evaluate the potential U.S. market opportunity for our Obalon balloon system, we commissioned a survey of 3,000 individuals. Each participant was asked to complete a survey containing a series of questions relating to income level, weight and interest in various weight loss alternatives. We took the results of that survey and applied them generally to the U.S. population figures for 2015 to estimate that there are approximately 11.0 million individuals in the United States with a household income greater than $30,000 and a BMI between 30 and 40 that would be interested in receiving treatment using the Obalon balloon system. We also used this information to estimate that the percentage of potentially interested individuals that are men or women is approximately the same. We cannot assure you that the individuals selected for the survey are representative of the characteristics and interests of the broader U.S. population, or that the responses of these individuals to our survey or our estimates are reliable or accurate. To the extent our assumptions regarding these individuals and data are inaccurate, our estimated market opportunity could be significantly different.

We have very limited experience as a company in the sales and marketing of our products, and no experience with sales and marketing in the United States. Identifying and recruiting qualified sales personnel and training them in the use of our Obalon balloon system to achieve the level of clinical competency expected by physicians, and compliance with applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense and attention. It can take several months before our sales representatives are fully trained and productive.

COMPETITION

The medical device industry is 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 relating to our industry. 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 those recently approved by the FDA, including Vivus, Inc., Arena Pharmaceuticals, Inc., Orexigen Therapeutics, Inc., and those with older brands or generics including Takeda Pharmaceutical Company Ltd, AstraZeneca plc, and Actavis plc. Large competitors in the surgical segment for weight loss and obesity include Ethicon Inc. (subsidiary of Johnson & Johnson), Medtronic plc (formerly Covidien Ltd.) and Apollo EndoSurgery, Inc., which acquired the Lap-Band from Allergan plc and currently sells that device worldwide. After approximately a decade, four new devices were approved by the FDA in 2015 and 2016. Enteromedics Inc. received FDA approval for the Maestro, which is intended to create weight loss by vagal nerve stimulation. ReShape Medical Inc. and Apollo EndoSurgery, Inc. received FDA approval for the ReShape Duo Balloon and the ORBERA Balloon, respectively, each a traditional intragastric balloon filled with saline. Aspire Bariatrics received FDA approval for the Aspire Assist, a device that allow you to aspirate food after a meal. Allurion Technologies, Inc. has also developed a swallowable, passable saline-filled intragastric balloon that has been approved for sale in Europe and Middle East. Additionally, there are many more companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, which 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 saline-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 advisors 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, 2016, we held 14 issued U.S. patents and had 19 pending U.S. patent applications, as well as 17 international patents issued in Europe, Mexico, Australia, Canada, Asia, China and Israel and 34 pending international patent applications in Australia, Canada, Europe, Asia, the Middle East and South America. Our issued patents expire between the years 2023 and 2032, 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 we continue to research and develop our Obalon balloon system technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of our balloon and navigation devices.

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, 2016, we held one registered U.S. trademark and 13 registered marks in Europe, Asia and Mexico. We have three pending U.S. trademark applications and 8 pending marks outside the United States, including in Europe, the Middle East, Asia and Mexico.

MANUFACTURING

All of our products are manufactured or assembled in-house using components and sub-assemblies at our facilities in Carlsbad, California. 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. Our suppliers 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. To date, we have not experienced significant delays in obtaining any of our components or subassemblies. However, 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 unannounced inspections that may include the manufacturing facilities of our subcontractors. Since we began manufacturing onsite, our quality system has undergone 15 external audits, the last of which occurred in November 2016 and resulted in no non conformances.

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

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.

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 devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, 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, as well as Special Controls, which can include performance standards, guidelines 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. 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 either:

- a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or
- another commercially available, similar device that was cleared 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) notice 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.

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. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. 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. If the FDA requires a new 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, the applicant may be required to cease marketing or recall the modified device until clearance or approval is received. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite PMA application(s). In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

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. Pursuant to amendments to the statute in 2012, 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.

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 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 commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- side effects or 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;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- third-party investigators are disqualified by the FDA;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations;
- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and efficacy.

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. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical trial data and clinical trial sites, and a QSR inspection 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 or any of its components, including modifications to our manufacturing processes, device labeling and device design.

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.
- The MDR regulations 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. In February 2017, the FDA issued a letter to Healthcare Practitioners citing they had received multiple reports for two different types of adverse events associated with traditional, saline-filled intragastric balloons. Although the letter specifically states that these adverse events have not been reported for the Obalon balloon system, this action may indicate closer scrutiny of the intragastric balloon category which could have detrimental effects on our efforts to commercialize our products or get new products approved.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. 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 CDHS to determine our compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of our suppliers. BSI, our European Notified Body, most recently inspected our facility in 2016 and found zero non-conformances. Our current facility has been inspected by the FDA in 2014 and 2016, and four observations were noted in the first inspection and zero observations were noted in the second inspection. Responses to the observations in the 2014 FDA audit were accepted by the FDA and no response was required by us in the 2016 inspection. We believe that we are in substantial compliance with the QSR.

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 25 member states 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 porcine capsule, is considered a Class III product. The Obalon balloon system when delivered with a cellulose-based capsule is considered a Class IIb product.

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.

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 Authorisation 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 have appointed Bader as our exclusive agent/distributor in Kuwait.

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

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, directed the Secretary of the U.S. Department of Health and Human Services, or HHS, to promulgate regulations establishing protections for the privacy and security of individually identifiable health information, known as "protected health information" and prescribing standard requirements for electronic health care transactions. HIPAA generally requires certain entities, referred to as "covered entities" (including most healthcare providers, healthcare clearing houses and health plans), to comply with established standards, including standards regarding the privacy and security of protected health information, or 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.

The American Recovery and Economic Reinvestment Act of 2009, or ARRA, signed into law by President Obama on February 17, 2009, contained significant changes to the privacy and security provisions of HIPAA, including major changes to the enforcement provisions. Among other things, ARRA significantly increased the amount of civil monetary penalties that can be imposed for HIPAA violations. ARRA also authorized state attorneys general to bring civil enforcement actions under HIPAA. These enhanced penalties and enforcement provisions went into effect immediately upon enactment of ARRA. ARRA also required that HHS promulgate regulations requiring that certain notifications be made to individuals, to HHS and potentially to the media in the event of certain types of breaches of the privacy of protected health information. These breach notification regulations went into effect on September 23, 2009, and HHS began to enforce violations on February 22, 2010. Violations of the breach notification provisions of HIPAA can trigger the increased civil monetary penalties described above.

The Health Information Technology for Economic and Clinical Health Act, or HITECH, was also enacted in conjunction with ARRA. On January 25, 2013, HHS issued final modifications to the HIPAA Privacy, Security, and Enforcement Rules mandated by HITECH, which had been previously issued as a proposed rule on July 14, 2010. Among other things, these modifications make business associates of covered entities directly liable for compliance with certain HIPAA requirements, strengthen the limitations on the use and disclosure of protected health information without individual authorizations, and adopt the additional HITECH enhancements, including enforcement of noncompliance with HIPAA due to willful neglect. The changes to HIPAA enacted as part of ARRA reflect a Congressional intent that HIPAA's privacy and security provisions be more strictly enforced. It is likely that these changes will stimulate increased enforcement activity and enhance the potential that health care providers will be subject to financial penalties for violations of HIPAA.

In addition to the federal laws and regulations, there are a number of state laws regarding the privacy and security of health information and personal data. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation, vary widely, and new privacy and security laws in this area are evolving.

We believe we are not a covered entity for purposes of HIPAA, and we believe that we generally do not conduct our business in a manner that would cause us to be a business associate under HIPAA. Although we do not believe the business is subject to HIPAA, we nevertheless are committed to maintaining the security and privacy of patients' health information.

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 of up to $50,000 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 of between $5,500 and $11,000 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 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 ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1 million). 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.

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, PPACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the medical device industry. PPACA, 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. Although the excise tax has been suspended for 2016 and 2017, absent further legislative action, the tax will be reinstated starting January 1, 2018.

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, PPACA 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, 2016, we had 91 employees, including 24 in manufacturing and operations, 32 in sales and marketing, 11 in research and development, 14 in clinical affairs, regulatory affairs and quality assurance and 10 in finance, general administrative and executive administration. All 91 employees are full time employees. 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, 2016, 2015 and 2014 and our total assets as of December 31, 2016 and 2015, 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 in January 2008. Our principal executive offices are located at 5421 Avenida Encinas, Suite F, Carlsbad, California 92008, and our telephone number is (760) 795-6558. Our website address is www.obalon.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this prospectus. 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, including our consolidated financial statements and the related nothighes 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

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 research and development, clinical trials, product engineering and building our manufacturing capabilities. We have also conducted a commercial launch of a previous generation of the Obalon balloon system in certain international markets, but our commercial sales experience in these international markets has been limited and our total revenue to date is approximately $14.0 million. We have incurred significant losses in each period since our inception in 2008, with net losses of $20.5 million, $15.6 million and $9.9 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of approximately $76.6 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop, seek and obtain regulatory approval for our Obalon balloon system and sell our Obalon balloon system internationally.

We expect our costs and expenses to increase in the future as we continue U.S. commercialization of our product, including the cost of a direct sales force and the expansion of our manufacturing facilities, and as we continue to expend substantial amounts on research and development, including conducting clinical trials of our products in development. As a result, we expect our losses to continue for the foreseeable future. In addition, as a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. 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 to date our business activities have been focused primarily on the development and regulatory approval of our Obalon balloon system. All of our revenue to date is, and we expect for the foreseeable future will be, attributable to sales of our Obalon balloon system and its component parts. Our commercial sales experience to date has been limited to sales to distributors in a limited number of countries outside the United States. We recently obtained premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, to market the current generation of our balloon system in the United States, and we expect that sales in the United States will account for a majority of our revenue for the foreseeable future. Our limited operating experience and lack of commercialization experience in what we expect will be our primary market make it difficult to evaluate our current business and predict our future prospects. A number of factors that are outside our control may contribute to fluctuations in our financial results, including:

- patient and physician demand for our Obalon balloon system, including the rate at which physicians recommend our Obalon balloon system to their patients;
- 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 patient experience with our Obalon balloon system;

- any safety or efficacy concerns for the category of intragastric balloons including traditional saline-filled balloon such as those safety issues stated in the February 2017 FDA Health Care Provider letter warning about pancreatitis and hyperinflation;
- unanticipated delays in product development or product launches;
- our ability to maintain our current or obtain further regulatory clearances or approvals;
- delays in, or failure of, product and component deliveries by our third-party suppliers;
- introduction of new procedures or products for treating obese or overweight patients that compete with our product;
- adverse changes in the economy that reduce patient demand for elective procedures; and
- performance of our international distributors.

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.

Physicians and 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 physician and patient adoption. If any of these events were to occur, our business and prospects would be negatively affected.

Intragastric balloons are a new treatment option for obese and overweight patients. Currently, we are aware of only two other intragastric balloons available for sale in the United States, neither of which was available prior to 2015. As a result, physician and patient awareness of intragastric balloons as a treatment option for obesity and weight management, and experience with intragastric balloons, is minimal. Our success depends in large part on our ability to educate physicians and patients, and successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our Obalon balloon system. Since we received PMA approval for the Obalon balloon system in September 2016, we began engaging in an active marketing campaign to raise awareness of our Obalon balloon system and its benefits among physicians, but we cannot assure you that these efforts will be successful or that they will not prove to be cost-prohibitive.

Physicians play a significant role in determining the course of a patient's weight management or obesity treatments and as a result, the type of treatment that will be recommended or provided to a patient. We intend to target our sales efforts at bariatric surgeons, gastroenterologists, and plastic surgeons, because they are either the physicians treating obese and overweight patients and/or have experience with endoscopic procedures. However, the initial point of contact for many obese and overweight patients may be general practitioners, bariatricians, endocrinologists, obstetricians and gynecologists, each of whom commonly manage and regularly see patients that are obese or overweight. If these physicians are not made aware of our Obalon balloon system, they may not refer patients to bariatric surgeons, gastroenterologists or plastic surgeons for treatment using our product, and those patients may instead not seek treatment at all or be treated with pharmaceuticals or an alternative device or surgical procedure.

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 and physicians may attribute such negative events to intragastric balloons generally, which may adversely affect market adoption of our Obalon balloon system. In February 2017, the FDA issued a letter to Healthcare Practitioners citing they had received multiple reports for two different types of adverse events associated with Reshape and Apollo saline-filled intragastric balloons. Although the letter specifically states that these events have not been reported for the Obalon balloon system, this action could create negative perceptions of the entire category and slow down the acceptance of the Obalon Balloon. Additionally, if patients undergoing treatment with our Obalon balloon perceive the weight loss inadequate or adverse events too numerous or severe as compared with the retreatment 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 are unable to convince physicians to adopt our Obalon balloon system and recommend it to their patients, we may be unable to sell our products, grow our business or achieve profitability.

Our ability to sell our Obalon balloon system depends heavily on the willingness of physicians to adopt our system and recommend it to their patients. Physicians may not adopt our Obalon balloon system unless they are able to determine, based on experience, long-term clinical data, recommendations from other physicians and published peer-reviewed journal articles, that it provides a safe and effective treatment alternative for obesity. Even if we are able to raise awareness among physicians, 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:

- long-standing relationships with competitors and distributors that sell other products and their competitive response and negative selling efforts;
- 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;
- 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; and
- time and skill commitment that may be required to gain familiarity with a new system.

We are also aware of certain characteristics and features of our Obalon balloon system that may prevent widespread market adoption. For example, our Obalon balloon system is approved as an adjunct to a moderate intensity diet and behavior modification program. As a result, physicians will need 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. If physicians are unable or unwilling to implement the appropriate practice management programs to successfully treat patients with the Obalon balloon, they may not adopt our balloon system. Our current EzFill inflation system requires certain pre-programming that is dependent upon the altitude of the physician's practice, which may hinder or make it more difficult for us to market and commercialize our products.

The effectiveness and safety of our Obalon balloon system depends critically on our ability to educate physicians on its safe and proper use. If we are unable to do so, we may not achieve our expected growth and may be subject to risks and liabilities.

In addition to educating physicians on the clinical benefits of our Obalon balloon system, we must also train physicians on its safe and appropriate use. In particular, our FDA approved labeling requires physicians to complete an Obalon training program before they can place the device and for us to provide clinical support as needed. If we are unable to provide an adequate training program, product misuse may occur that could lead to SADEs. Many physicians may be unfamiliar with such treatments or find it more complex than competitive products or alternative treatments. As such, there is a learning process involved for physicians to become proficient in the use of our products and it may take several procedures for a physician to be able to use our Obalon balloon system comfortably. 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 energy 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. In the event that 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 may experience adverse events or not be able to enjoy the benefits of our system or achieve the weight loss outcomes they expect, leading to dissatisfaction and market rejection of our products. In addition, misuse of our products in any stage of the treatment may 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.

If patients are unable to successfully swallow the capsule, our device malfunctions during delivery or physicians cannot deploy the Obalon balloon, physicians may be unwilling to continue to recommend our products.

Patients may be unable to successfully swallow the capsule that contains the Obalon balloon, potentially creating an economic disincentive for physicians in adopting our technology. In our SMART 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. There were also instances where balloon deployment was negatively impacted due to a leak in the microcatheter, which was caused by the patient biting the catheter during placement. There may be other reasons for unsuccessful placements that 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. Alternatively, physicians that have paid us for a balloon, but have not been paid by their patient because of a treatment

failure, may seek a refund or monetary damages from us. Either scenario could cause a negative financial impact for us and could also create ill will with patients and physicians.

Patients may experience SADEs as the result of the misuse or malfunction of, or design flaws in, our products, which 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. 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. Esophageal perforation leading to sepsis and death associated with the sepsis has been reported with use of our product. Balloon deflation and migration into the lower intestine requiring surgical removal has also been reported with 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 have in the past have 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 or reduce gross margins. Our inability to remedy a product defect could result in the financial failure of products, a product recall, temporary or permanent withdrawal of a product from a market, product liability suits, damage to our reputation or our brand, inventory costs or product reengineering expenses, any of which could have a material impact on our business, results of operations and financial condition.

If we fail to grow our sales and marketing capabilities and develop widespread brand awareness cost effectively, our growth will be impeded and our business may suffer.

We have very limited experience as a company in the sales and marketing of our products. The majority of our product sales to date have been through a single international distributor in the Middle East, with a lesser percentage sold through distributors or directly to physicians in Europe and Mexico. We recently obtained FDA approval to market our Obalon balloon system in the United States, and commercialized in select U.S. states in January 2017 through a direct sales force. Training our U.S. sales force in use of our Obalon balloon system to achieve the level of clinical competency expected by physicians, and to comply with applicable federal and state laws and regulations and our internal policies and procedures requires significant time, expense and attention. It can take several months before our sales representatives are fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenues. In particular, there is significant competition for qualified and experienced sales personnel. If we are unable to hire, develop and retain talented sales personnel or if new sales 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.

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

- the inability of our sales and marketing personnel to perform their duties and conduct business in a manner that is compliant with our internal policies and procedures and FDA law and regulations;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to recommend any current and future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- efforts by our competitors to commercialize products at or about the time when our product would be coming to market.

Our ability to increase our customer base and achieve broader market acceptance of our Obalon balloon system will depend to a significant extent on our ability to expand our marketing programs. We plan to dedicate significant financial and other resources to our marketing programs. Our business will be harmed if our marketing efforts and expenditures do not generate an increase in revenue.

In addition, we believe that developing and maintaining widespread awareness of our brand in a cost-effective manner is critical to achieving widespread 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 or retain the customers necessary to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad customer adoption of our Obalon balloon system.

We actively employ social media 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 rules, 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 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 physicians or patients will receive third-party reimbursement for treatment with our products. As a result, we expect that our success will depend on the ability and willingness of physicians to adopt self-pay practice management infrastructure and 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 payors will cover or reimburse physicians or patients for the Obalon balloon system. As a result, we expect that our success will depend on the ability and willingness of physicians that may not have historically operated a self-pay practice to adopt the policies and procedures needed to successfully operate such a practice. Our initial sales and marketing efforts in the United States are targeted at bariatric surgeons, gastroenterologists and plastic surgeons. Bariatric surgeons and gastroenterologists are accustomed to providing services that are reimbursed by third-party payors. As a result, these physicians may need to augment their administrative staff and billing procedures to address the logistics of a self-pay practice. If physicians are unable or unwilling to make such changes, adoption of our products may be slower than anticipated.

Our success will also depend on the ability and willingness of patients to pay out-of-pocket for treatment with our products. 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 physicians offer the Obalon balloon system to their patients;
- the extent to which the Obalon balloon system satisfies patient expectations;
- 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 physician or patient demand for the Obalon balloon system.

We have limited experience manufacturing our Obalon balloon system in commercial quantities.

All of our product sales through December 31, 2016 have occurred internationally using an earlier generation of the Obalon balloon system. We transitioned to production of the current generation of the Obalon balloon system in November 2016. As a result, we have limited experience in manufacturing the current Obalon balloon system in commercial quantities, and we will need to increase our manufacturing capabilities in order to satisfy expected demand for our Obalon balloon system. We may encounter production delays or shortfalls caused by many factors, including the following:

- 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;
- 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; and
- our ability to attract and retain qualified employees, who are in short supply, in order to increase our manufacturing output.

If we are unable to keep up with demand for our Obalon balloon system, our revenue could be impaired, 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. 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. 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. For example, given that we have received PMA approval for our Obalon balloon system, 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 subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to consistently produce quality components that meet our specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;

- 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; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

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. 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 may not be able to secure additional financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our commercialization efforts and product development programs.

Our operations have consumed substantial amounts of cash since inception. We believe that the net proceeds from our initial public offering, or IPO, together with our existing cash and cash equivalents and short-term investments and expected revenue, will be sufficient to meet our capital requirements and fund our operations through the next two years. Since we commenced U.S. commercialization of our Obalon balloon system in January 2017, we expect our costs and expenses to increase in the future, including the development of a direct sales force, increased marketing programs, the expansion of our manufacturing facilities, and as we continue to expend substantial amounts on research and development, including for conducting clinical trials, of our products in development. We also may need additional funds to complete the development and commercialization of advancements to our existing Obalon balloon system as well as our additional products under development. Additionally, we will continue to incur costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the costs and expenses of our U.S. sales and marketing infrastructure and our manufacturing operations;
- the degree of success we experience in commercializing our Obalon balloon system;
- the revenue generated by sales of our Obalon balloon 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 developing enhancements of our Obalon balloon 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 is adopted by the physician community and patients;
- the number and types of future products we develop and commercialize;
- 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; and
- the extent and scope of our general and administrative expenses.

Additional financing may not be available on a timely basis on terms acceptable to us, or at all. We may raise funds in equity or debt financings 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. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or 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.

A majority of our historical revenue in 2016 and 2015, prior to our U.S. Launch in January 2017 was derived from a single distributor that is also one of our principal stockholders

Bader Sultan & Bros. Co. W.L.L., or Bader, is currently the sole distributor of our Obalon balloon system in the Middle East. Revenue received from Bader's distribution of our Obalon balloon system in the Middle East represented 100% of our total revenue for the year ended December 31, 2016 and a majority of our total revenue for the year ended December 31, 2015. We have discontinued sales of our prior generation product in the Middle East and do not plan to begin selling in the Middle East again until our next generation inflation system is approved. We are currently working closely with Bader to determine the best timing and strategy for launch of the current generation Obalon balloon system with the next generation inflation system in the Middle East. We have limited control over Bader's sales and marketing efforts for our product. If Bader fails to effectively market and sell our products in full compliance with applicable laws, or if we are unable to maintain our existing relationship with Bader, we may not be able to find a distributor with the scale and resources of Bader, maintain existing levels of international revenue or realize expected long-term international revenue growth. In addition, since the Obalon balloon system is our sole source of revenue, a delay or failure by Bader to successfully market our Obalon balloon system or the loss of Bader as a distributor could have a significant impact on our revenues and financial health.

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 product development and regulatory strategy, we plan to 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.

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 is 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 relating to our industry. 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 those recently approved by the FDA, including Vivus, Inc., Arena Pharmaceuticals, Inc., Orexigen Therapeutics, Inc., and those with older brands or generics including Takeda Pharmaceutical Company Ltd, AstraZeneca plc, and Actavis plc. Large competitors in the surgical segment for weight loss and obesity include Ethicon Inc. (subsidiary of Johnson & Johnson), Medtronic plc (formerly Covidien Ltd.) and Apollo EndoSurgery, Inc., which acquired the Lap-Band from Allergan plc and currently sells that device worldwide. After approximately a decade, four new devices were approved by the FDA in 2015 and 2016. Enteromedics Inc. received FDA approval for the Maestro, which is intended to create weight loss by vagal nerve stimulation. ReShape Medical Inc. and Apollo EndoSurgery, Inc. received FDA approval for the ReShape Duo Balloon and the ORBERA Balloon, respectively, each a traditional saline-filled intragastric balloon. Aspire Bariatrics received FDA approval for the Aspire Assist, a device that allows a patient to aspirate food after a meal. Allurion Technologies, Inc. has also developed a swallowable, passable saline-filled intragastric balloon that has been approved for sale in Europe and the Middle East. Additionally, there are many more companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, which 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 currently 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, with final assembly completed at our facility. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, 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.

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 particular, our President and Chief Executive Officer, Andrew Rasdal, who has been with us since inception, has been instrumental in building operational capabilities, raising capital and guiding product development and regulatory strategy. We do not currently maintain key personnel life insurance policies on any of our employees, including Mr. Rasdal.

To execute our 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 executives. 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. Furthermore, replacing executive officers and key employees may be 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.

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, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, either because we are a public company or otherwise, it may harm our ability to recruit and retain 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.

If we are unable to manage the anticipated growth of our business, our future revenues and results of operations may be harmed.

We have been growing rapidly in recent periods and have a relatively short operating history as a commercial company, with no history as a commercial company in the United States. We intend to continue to grow our business and may experience periods of rapid growth and expansion. Future growth will impose significant additional responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative personnel, information technology systems and other operational infrastructure. We must successfully expand our sales force to achieve broad market penetration and geographical coverage within the United States. We must also successfully increase manufacturing output to meet expected customer demand, and may experience difficulties with yields, quality control, component supply and shortages of qualified personnel, among others. Any failure to manage our expected growth effectively 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.

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 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.

Our Obalon balloon system may in the future be subject to product recalls that could harm our reputation.

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 or design or labeling defects. 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. A recall announcement would 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 testing, manufacturing and marketing 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. For example, we rely on physicians in connection with the placement of our Obalon balloon into patients. If these physicians are not properly trained or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury. 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 or inflated in the body other than in the stomach or if it deflates 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, any recall or market withdrawal of 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 an adverse effect on our business, results of operations and financial condition.

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 post-market safety and efficacy data be collected 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.

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 the 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 harmed.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

In September 2016 and December 2016, we amended our loan and security agreement with Pacific Western Bank (as successor in interest to Square 1 Bank), pursuant to which an additional $5.0 million was made available to us, which has not been drawn down. As of December 31, 2016, we had $10.0 million in principal and interest outstanding under our loan and security agreement. We are required to make interest-only monthly payments on the outstanding debt through June 2018, followed by 30 equal monthly installments of principal and interest, which diverts a portion of our resources from other activities. Our debt with Pacific Western Bank is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, incur additional indebtedness, change the name, location, office or executive management of our business, change our business, merge with or acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with our affiliates, create liens, sell assets, pay any subordinated debt and store certain inventory and equipment with third parties. These covenants may make it difficult to operate our business. We are also subject to standard event of default provisions under the credit agreement that, if triggered, would allow the debt to be accelerated, which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. The existing collateral pledged under the credit agreement, and the covenants to which we are bound may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions, heighten our vulnerability to downturns in our business or our industry or the general economy, limit our ability to adjust to changing market conditions and place us at a competitive disadvantage compared to our competitors who have greater capital resources.

If there are significant disruptions in our information technology systems, 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, 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 or hackers, power losses, and computer system or data network failures. 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.

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 and the further development of our product could be delayed. 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. 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 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 margin may be adversely impacted.

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

If 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;
- 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 unrelated 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, beginning with our annual report for the year ending December 31, 2017, 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.

We are in the process of designing and implementing our internal control over financial reporting, which will be time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we 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.

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

At December 31, 2016, we had federal and state net operating loss carryforwards, or NOLs, of approximately $58.7 million and $14.4 million, respectively. Each of the federal and state NOLs will begin expiring in 2028, unless previously utilized. We also had federal and California research and development tax credit carryforwards totaling $1.8 million and $1.6 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 APPROVAL

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. We have filed a PMA-Supplement for approval of our vegetable-based HydroxyPropylMethylCellulose, or HPMC, capsule, which is expected to replace the current animal-based gelatin capsule. It is not anticipated that human clinical data will be required for approval of this PMA-Supplement and the primary information used to support the approval will be in vitro testing. However, it is possible that the FDA may require this information, which could delay potential approval or we may fail to receive regulatory clearance at all. To support a potential request for human data, we evaluated the HPMC capsule in our SMARTCAR study. In the future, we intend to file a PMA-Supplement for approval of the Obalon Touch Inflation System, our next generation inflation system that is expected to replace the EzFill inflation system used to inflate the balloon with gas. The Obalon Touch is a refinement of the EzPz Dispenser project based on the learning from actual usage. It is not anticipated that human clinical data will be required for approval and we expect the PMA-Supplement to based primarily on in vitro testing including, but not limited to, software validation and human factors assessment. However, it is possible that the FDA may require this information, which could delay potential approval. While we expect to successfully complete the in vitro testing required to submit a PMA supplement for the Obalon Touch inflation system, there can be no guarantee that these product enhancements will be completed or that we will receive regulatory approval for the sale and marketing of the Obalon Touch inflation system in the United States or in other regulatory jurisdictions outside the United States. 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. Because we are depending on Obalon Touch inflation system, HPMC capsule and other new products to achieve our revenue goals in future years, failure to receive FDA approval or regulatory approval in jurisdictions outside the United States, in a timely manner or at all, will harm our financial results and ability to become profitable. Even if we obtain such regulatory approval, our ability to successfully market the Obalon balloon system may be limited. If we cannot sell our Obalon balloon system with Obalon Touch inflation system, the HPMC capsule and other new products as planned, our financial results could be harmed.

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 12 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 agreed with the FDA to conduct a post-approval study at 10 to 15 sites in the United States to evaluate the safety and efficacy of our Obalon balloon system in 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 will be required to update

our product labeling in a PMA supplement as results, including any adverse event data, from the post-approval study become available.

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.

Material modifications to our Obalon balloon 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 clearance or approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires premarket clearance or approval from the FDA pursuant to a new 510(k) clearance or approval of a PMA supplement. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, notice in an annual report or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. Any modification to a PMA approved device requires a PMA supplement, notification to the FDA in a PMA annual report, or possibly a new PMA. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or obtain approval of PMA supplements or new PMAs for modifications to, or additional indications for, our Obalon balloon system in a timely fashion, or at all. Delays in obtaining required future clearances 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 clearances or approvals and the FDA disagrees and requires new clearances or 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. In these circumstances, we may be subject to significant enforcement actions.

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 is a medical device that is 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.

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. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at 10 to 15 sites in the United States to evaluate the safety and efficacy of our Obalon balloon system in 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. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data, from the post-approval study become available. Failure to conduct the post-approval study 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 harm our business.

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 publically 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.

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, 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, 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.

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.

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, recordkeeping, 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 recordkeeping 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 in 2014 and 2016, with four and zero inspectional observations, respectively, noted during those inspections. 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 or warning letters;
- 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 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.

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

Healthcare providers, physicians and others will play a primary role in the recommendation and ordering of, and treatment using, our Obalon balloon system. Although intragastric balloon products similar to our Obalon balloon system are not currently reimbursed by United States 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 United States federal and state healthcare laws and regulations 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, under the Patient Protection and Affordable Care Act, as amended, or PPACA, 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.

- ***Privacy and Security Laws.*** The Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and accompanying regulations, which we collectively refer to as HIPAA, require 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 protected health information, or 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 we generally do not conduct our business in a manner that would cause us to be a Business Associate under HIPAA, but we are nevertheless committed to maintaining the security and privacy of patients' health information. Although we believe the business is not currently subject to HIPAA, there is no guarantee that government enforcement agencies will agree. Violation of HIPAA could result in the imposition of civil or criminal penalties.

  In addition, many state laws regulate the use and disclosure of health information and require notification in the event the confidentiality of such information is breached. Those state laws that are more protective of individually identifiable health information are not preempted by HIPAA. Violation of applicable state privacy laws also may result in significant fines and other penalties.

- ***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, which was enacted as part of PPACA, 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 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, 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, 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.

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, 2016, we held 14 issued U.S. patents and had 19 pending U.S. patent applications, as well as 17 international patents issued in Europe, Mexico, Australia, Canada, Asia, China and Israel and 34 pending international patent applications in Australia, Canada, Europe, Asia, the Middle East and South America. Our issued patents expire between the years 2023 and 2032.

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 covered by 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 upon 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 exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may 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, 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 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's 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 U.S. 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 U.S. 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 detect infringement. It may be difficult to detect 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 may preemptively 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 re-examination, 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 recently enacted and is currently 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 U.S. 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

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 is affected by a number of factors, including:

- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- 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 traditional saline-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;

- developments, announcements or disputes related to patents or other proprietary rights issued to us or our competitors and to litigation; 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 securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, 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. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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.

All of the stockholders who held shares of our capital stock prior to our IPO are subject to a market standoff and/or lock-up agreement with the underwriters of our IPO that restrict such stockholders' ability to transfer shares of our common stock. Subject to certain limitations, approximately 11 million shares will become eligible for sale beginning on April 4, 2017. In addition, shares issued or issuable upon exercise of options vested as of the expiration of the lock-up period will be eligible for sale at that time. 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 and the 180-day lock-up period under the lock-up agreements described above.

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.

We also expect that significant additional capital may be needed in the future to continue our planned operations. 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. 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.

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 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, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a majority of our outstanding capital stock. As a result, this group of stockholders will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control 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 could be subject to securities class action litigation.

In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it 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 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, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one which is vested in the exclusive jurisdiction of 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. In addition, our loan and security agreement with Pacific Western Bank prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. 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 17,500 square foot facility in Carlsbad, California. The term of the lease for our facility extends through March 2019. Our facility houses our research and development, sales, marketing, manufacturing, finance and administrative activities. We believe that our current facilities are adequate for our current needs.

ITEM 3. Legal Proceedings

From time to time, we are involved in legal proceedings in the ordinary course of business. We are currently not a party to any legal proceedings that we believe would have a material adverse effect on our business, financial condition or results of operations.

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.

The following table sets forth for the indicated periods the high and low sales price of our common stock on The NASDAQ Global Market.

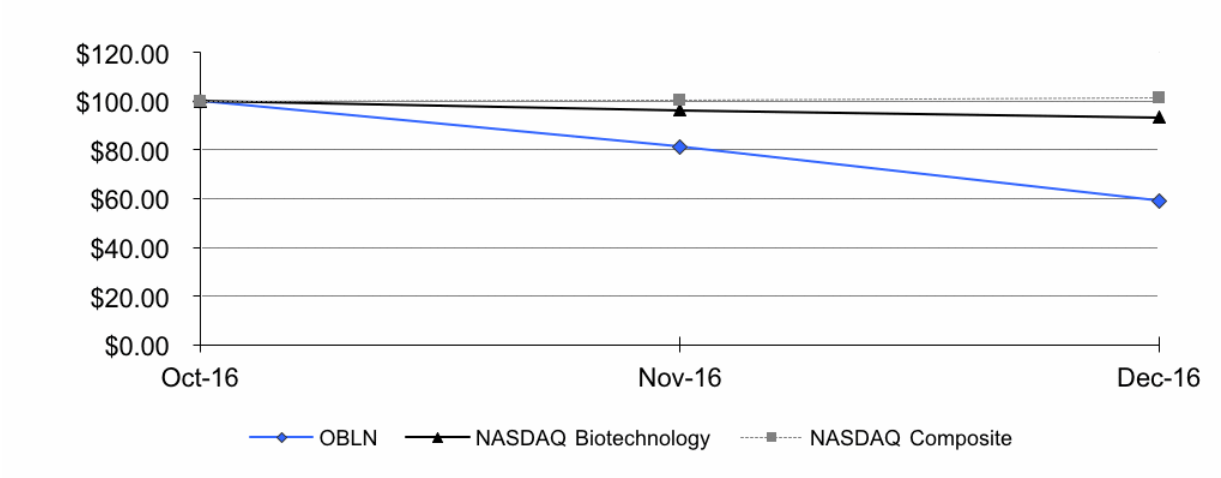
	High	Low
Year ended December 31, 2016		
Fourth quarter (from October 6, 2016)	$ 15.88	$ 8.27

On February 17, 2017, the last reported sale price of our common stock was $9.31.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Obalon Therapeutics, Inc. under the Securities Act or the Exchange Act.

The following graph shows a comparison from October 6, 2016 (the date our common stock commenced trading on The NASDAQ Global Market) through December 31, 2016 of the cumulative total return for our common stock and NASDAQ Biotechnology Index and NASDAQ Composite. The graph assumes that $100 was invested at the close of market on October 6, 2016 in the common stock of Obalon Therapeutics, Inc., NASDAQ Biotechnology Index and NASDAQ Composite. The stock price performance of the following graph is not necessarily indicative of future stock price performance.



Cumulative Total Return Comparison

	October 16, 2016	December 31, 2016
Obalon Therapeutics, Inc.	$ 100.00	$ 59.00
NASDAQ Biotechnology	$ 100.00	$ 93.23
NASDAQ Composite	$ 100.00	$ 101.44

Holders of Record

As of February 17, 2017, there were approximately 60 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 2017 Annual Meeting of Stockholders. See Part III, Item 12 "Security Ownership of Certain Beneficial Owners and Management."

Recent Sales of Unregistered Securities

From January 1, 2016 to December 31, 2016, we granted to our directors and employees options to purchase 740,782 shares of common stock under our 2008 Stock Plan with a weighted-average per share exercise price of $1.85. In the same period, we issued and sold 808,885 shares of common stock upon exercise of stock options issued under the 2008 Stock Plan to our directors, officers, employees, consultants and other service providers for cash consideration at prices ranging from $0.76 to $2.61 for an aggregate purchase price of $1.1 million. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Rule 701 promulgated under the Securities Act of 1933, as amended.

On April 29, 2016 and May 4, 2016, we issued in two closings an aggregate of 1,916,425 shares of Series E convertible preferred stock at a purchase price of $8.2932 per share for an aggregate purchase price of $15.8 million to 12 purchasers that represented to the Registrant that they were each an accredited investor. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act.

Use of Proceeds

On October 5, 2016, our Registration Statement on Form S-1 (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. UBS Securities LLC, Canaccord Genuity Inc. and Stifel, Nicolaus & Company, Incorporated acted as joint book-running managers of the offering and as representatives of the underwriters. BTIG LLC acted as co-manager for the offering. The offering did not terminate before all of the securities registered in the Registration Statement were sold. On October 12, 2016, we closed the sale of such shares, resulting in net proceeds to us of $67.2 million, after deducting underwriting discounts and commissions of approximately $5.2 million, and offering costs of approximately $2.6 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO, as described in our final Prospectus filed with the SEC on October 6, 2016 pursuant to Rule 424(b).

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, 2016, 2015 and 2014 and the selected consolidated balance sheet data as of December 31, 2016 and 2015 from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated balance sheet data as of December 31, 2014 is derived from our audited consolidated financial statements which are 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,		
	2016	2015	2014
Consolidated statements of operations data:			
Revenue:			
Revenue	$ —	$ 216	$ 1,683
Revenue, related party	3,393	3,823	1,856
Total revenue	3,393	4,039	3,539
Cost of revenue	2,809	2,503	2,912
Gross profit	584	1,536	627
Operating expenses:			
Research and development	9,872	12,978	5,767
Selling, general and administrative	10,217	3,491	4,700
Total operating expenses	20,089	16,469	10,467
Loss from operations	(19,505)	(14,933)	(9,840)
Interest expense, net	(477)	(549)	(220)
(Loss) gain from change in fair value of warrant liability	(466)	(34)	167
Other (expense) income, net	(19)	(41)	3
Net loss	(20,467)	(15,557)	(9,890)
Other comprehensive (loss) income	(1)	5	9
Net loss and comprehensive loss	$ (20,468)	$ (15,552)	$ (9,881)
Net loss per share, basic and diluted(1)	$ (4.85)	$ (27.14)	$ (18.61)
Weighted-average common shares outstanding, basic and diluted(1)	4,221,893	573,181	531,430

(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,		
	2016	2015	2014
Consolidated balance sheet data:			
Cash and cash equivalents and short-term investments	$ 75,475	$ 12,531	$ 19,244
Working capital	73,469	8,236	19,364
Total assets	78,778	14,221	20,719
Term loan	9,881	9,841	4,877
Warrant liability	—	332	56
Convertible preferred stock	—	54,699	54,826
Accumulated deficit	(76,609)	(56,142)	(40,585)
Total stockholders' equity (deficit)	64,305	(55,139)	(39,856)

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 obese and overweight people. Our initial 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 obese patients. In September 2016, we received premarket approval from the FDA to market our balloon system for temporary use to facilitate weight loss in obese adults with a body mass index, or 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. The Obalon balloon system has the potential to provide patients and physicians with a cost-effective, reversible and repeatable weight loss solution in an outpatient setting, without altering patient anatomy or requiring surgery. We commenced the U.S. commercial launch of our Obalon balloon system with both initial shipments to physicians and first commercial patient placements by physicians in January 2017. As of December 31, 2016, we had sold over 26,000 of our earlier generation Obalon balloon systems for commercial use outside the United States.

We began selling an earlier version of our Obalon balloon system in international markets in the third quarter of 2012. In 2015, we discontinued sales in certain international markets to conserve financial resources. We continued distribution of our earlier generation product in the Middle East through December 2016 while we focused on developing our current Obalon balloon system for the United States market. We have discontinued sales of our prior generation product in the Middle East and do not plan to begin selling in the Middle East again until our next generation inflation system is approved. We are currently working closely with Bader Sultan & Bros. Co W.L.L., or Bader, to determine the best timing and strategy for launch of the current generation Obalon balloon system with the next generation inflation system in the Middle East.

In June 2013, we entered into a distribution agreement with Bader, a healthcare products distributor based in Sufat, Kuwait, which subsequently became one of our significant stockholders. Pursuant to the distribution agreement, in November 2013, we began selling our earlier generation Obalon balloon system to Bader, our sole distributor in the Middle East. Sales to Bader for the years ended December 31, 2016, 2015 and 2014 totaled $3.4 million, $3.8 million and $1.9 million, which represented 100%, 94.7% and 52.4% of total revenue, respectively. For the year ended December 31, 2016, all of our total revenue consisted of sales of our earlier generation Obalon balloon system to Bader. We expect Bader to account for a significantly lower percentage of our total revenue in the future as we commenced commercial sales in the United States in January 2017.

We intend to focus our sales and marketing efforts primarily on selling our product in the United States through a direct sales force, as well as selling our products through Bader in the Middle East and other distributors in select international markets. We have built a direct sales organization consisting of regional sales directors, executive account managers and product specialists. We are selling the Obalon balloon system on a self-pay basis into existing physician specialty areas with weight loss practices, such as bariatric surgeons and gastroenterologists. In addition, we are selling to plastic surgeons, due to their client base and experience managing self-pay and cash pay practices. Given the initial focus of our sales and marketing efforts, we are targeting the U.S. market with a sales organization of approximately 25 individuals.

We generated total revenue, including revenue recognized from related parties, of $3.4 million, $4.0 million and $3.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. For the years ended December 31, 2016, 2015 and 2014, our net loss was $20.5 million, $15.6 million and $9.9 million, respectively. We have not been profitable since inception, and as of December 31, 2016, our accumulated deficit was $76.6 million. From inception through December 31, 2016, we financed our operations primarily through private placements of our preferred securities, the sale of common stock in our initial public offering, or IPO in October 2016, and, to a lesser extent, debt financing arrangements.

On October 5, 2016, our Registration Statement on Form S-1 relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 5,000,000 shares of our common stock at a price of $15.00 per share for aggregate cash proceeds of approximately $67.2 million, net of underwriting discounts, commissions, and offering costs. The IPO closed on October 12, 2016.

We expect to continue to incur net losses for the foreseeable future as we commercialize our product in the United States, including supporting our sales and marketing efforts in the United States, continuing research and development efforts, and seeking regulatory approval for new products and product enhancements. We may need additional funding to pay expenses relating to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding, if needed, may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms could have a material adverse effect on our business, results of operations or financial condition.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Revenue

Total revenue consists of international sales of an earlier generation of our Obalon balloon system. Revenue consists of sales of our Obalon balloon system to distributors or directly to physicians in international markets outside of the Middle East, and revenue, related party reflects sales of our Obalon balloon system to Bader in the Middle East. During the third quarter of 2015, we discontinued sales in international markets other than the Middle East, and for the year ended December 31, 2016, total revenue consisted of sales of our Obalon balloon system to Bader in the Middle East.

In January 2017 we shifted our focus to selling our Obalon balloon system in the United States, which we anticipate will be our primary market. We expect that, as a result, total revenue will increase as we implement our U.S. sales strategy and our revenue from international sales will constitute a smaller percentage of total revenue. However, the degree to which our revenue increases depends on many factors, including acceptance of our Obalon balloon system by doctors and patients, the emergence of competing products and general economic trends.

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 manufacturing overhead that directly supports 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 supervision and management, material procurement, inventory control, allocated quality assurance costs associated with manufacturing our product, facilities and depreciation on production equipment. We expect cost of revenue to increase in absolute dollars to the extent our total revenue grows but decrease as a percentage total of revenue over time as the fixed portion of our overhead costs is allocated over a greater number of units.

We calculate gross margin as gross profit divided by total revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, 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 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 continue to introduce new products, obsolete old products and adopt new manufacturing processes and technologies.

In January 2017, we began offering a swallow guarantee program in the United States where we may replace some balloons that cannot be swallowed by patients, subject to certain requirements and restrictions. As a result of this program our financial results or gross margin may be adversely impacted.

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. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products and enhance existing products and technologies. However, we expect R&D expenses as a percentage of total revenue to

vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense. Other SG&A expenses include promotional activities, marketing, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and allocated facilities-related expenses. We have grown our sales and marketing headcount and programs significantly in the recent quarter in preparation for the commercial launch of our Obalon balloon system in the United States which occurred in January 2017. As a result, SG&A expenses have grown significantly in the recent quarter, and are expected to continue to increase in absolute dollars and as a percentage of total revenue for the foreseeable future as we continue to expand our sales and marketing infrastructure to drive and support anticipated growth in revenue and due to the additional legal, accounting, insurance and other expenses associated with being a public company.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of our financial condition and results of operations is based on our 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

Revenue relates to sales of components of the Obalon balloon system, which includes the balloon and accessory kit, EzFill inflation system, pre-filled can of gas and placebo capsule. For the year ended December 31, 2016, the product was sold to one customer, Bader, a related party and healthcare product distributor based in Sufat, Kuwait. We recognize revenue when the following criteria are met:

- ***Persuasive evidence of an arrangement exists.*** We consider this criterion satisfied when we have an agreement or contract in place with the customer.
- ***Delivery has occurred.*** Our standard terms specify that title and risk of loss transfers upon shipment to customer. We use third-party shipping documents to verify that title has transferred.
- ***The selling price is fixed or determinable.*** We assess whether the sales price is fixed or determinable at the time of the transaction. Sales prices are documented in the executed sales contract or purchase order received prior to shipment. Our standard terms do not allow for trial or evaluation periods, rights of return or refund, payments contingent upon the customer obtaining financing or other terms that could impact the customer's obligation.
- ***Collectability is reasonably assured.*** We assess whether collection is reasonably assured based on a number of factors, including the customer's past transaction history and credit worthiness.

Stock-based compensation expense

We maintain an equity incentive plan to provide long-term incentive for employees, members of our board of directors and consultants. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to non-employee directors and consultants.

We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards, including employee stock options. We recognize this expense over the requisite service period. In addition, we recognize stock-based compensation expense in the statements of operations and comprehensive loss based on awards expected to vest and, therefore, the amount of expense has been reduced for estimated forfeitures. We use the straight-line method for expense attribution.

The valuation model we used for calculating the fair value of awards for stock-based compensation expense is the Black-Scholes option-pricing model, or the Black-Scholes model. The Black-Scholes model requires us to make assumptions and judgments about the variables used in the calculation, including:

- ***Expected term.*** We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based measurement of our options. Therefore, we have opted to use the "simplified method" for estimating the expected term of options, which is the average of the weighted-average vesting period and contractual term of the option.

- ***Expected volatility.*** Since there has been no public market for our common stock and lack of company specific historical volatility, we have determined the share price volatility for options granted based on an analysis of the volatility of a peer group of publicly traded companies. In evaluating similarity, we consider factors such as stage of development, risk profile, enterprise value and position within the industry.

- ***Risk-free interest rate.*** The risk-free interest rate is 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.

- ***Dividend rate.*** We assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.

- ***Expected forfeiture rate.*** We are required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, we record the difference as a cumulative adjustment in the period that the estimates are revised.

- ***Service period.*** We amortize all stock-based compensation over the requisite service period of the awards, which is generally the same as the vesting period of the awards. We amortize the stock-based compensation cost on a straight-line basis over the expected service periods.

- ***Fair value of common stock.*** Prior to the completion of our initial public offering, the fair value of the common stock underlying our stock options has historically been determined by our board of directors after considering, among other things, contemporaneous valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; our results of operations and financial condition, including our levels of available capital resources; equity market conditions affecting comparable public companies; general U.S. market conditions and the lack of marketability of our common stock; and valuations obtained from sales of our preferred stock to unrelated parties. For stock awards after the completion of our initial public offering, our board of directors determines the fair value of each share of underlying common stock based on the closing price of our common stock as reported on The NASDAQ Global Market on the date of grant.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change. We have not recognized, and we do not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on our deferred tax assets including deferred tax assets related to our net operating loss carryforwards.

Research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued R&D expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued R&D expenses include the costs incurred for services performed by our vendors in connection with R&D activities for which we have not yet been invoiced.

We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct R&D on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the R&D expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there has been no material differences between our estimates of such expenses and the amounts actually incurred.

Income taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance.

Due to the uncertainty surrounding possible Internal Revenue Code of 1986, as amended, or IRC, section 382 and 383 limitations on the use of our U.S. federal and state tax net operating loss carryforwards and tax credits, such tax loss carryforwards and tax credits have been removed from the deferred tax assets as of December 31, 2016 and December 31, 2015.

In general, under Sections 382 and 383 of the IRC, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or 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 and 383 have occurred.

If ownership changes within the meaning of IRC Section 382 and 383 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.

RESULTS OF OPERATIONS

	Year ended December 31,		
	2016	2015	2014
Consolidated statements of operations data:			
Revenue:			
Revenue	$ —	$ 216	$ 1,683
Revenue, related party	3,393	3,823	1,856
Total revenue	3,393	4,039	3,539
Cost of revenue	2,809	2,503	2,912
Gross profit	584	1,536	627
Operating expenses:			
Research and development	9,872	12,978	5,767
Selling, general and administrative	10,217	3,491	4,700
Total operating expenses	20,089	16,469	10,467
Loss from operations	(19,505)	(14,933)	(9,840)
Interest expense, net	(477)	(549)	(220)
(Loss) gain from change in fair value of warrant liability	(466)	(34)	167
Other (expense) income, net	(19)	(41)	3
Net loss	(20,467)	(15,557)	(9,890)
Other comprehensive (loss) income	(1)	5	9
Net loss and comprehensive loss	$ (20,468)	$ (15,552)	$ (9,881)

Comparison of years ended December 31, 2016 and 2015

Total revenue. Total revenue decreased $0.6 million to $3.4 million during the year ended December 31, 2016, compared to $4.0 million during the year ended December 31, 2015. This decrease was primarily attributable to a decrease in the volume sold as we discontinued sales of our previous generation product in international markets outside the Middle East beginning in the third quarter of 2015. In 2016, we also reduced the volume sold in the Middle East in preparation for transition to our current generation product in 2017, which was partially offset by an increase in the price per unit sold.

Cost of revenue. Cost of revenue increased $0.3 million to $2.8 million during the year ended December 31, 2016, compared to $2.5 million during the year ended December 31, 2015. This increase was primarily attributable to increased payroll costs and changes in the allocation of production cost between R&D expense and cost of revenue. Cost of revenue was also impacted by increased expenses associated with FDA approval including employee related expenses and write-down of obsolete materials.

Research and development expenses. R&D expenses decreased $3.1 million to $9.9 million during the year ended December 31, 2016, compared to $13.0 million during the year ended December 31, 2015. This decrease was primarily due to a decrease of $4.6 million in clinical trials expenses as we concluded the SMART trial, partially offset by an increase of $1.1 million in headcount related expenses and an increase of $0.4 million to supplies and outside consultant expenses.

Selling, general and administrative expenses. SG&A expenses increased $6.7 million to $10.2 million during the year ended December 31, 2016, compared to $3.5 million during the year ended December 31, 2015. This increase was primarily attributable to a $3.0 million increase in headcount related expenses in preparation for U.S. commercialization, a $1.3 million increase in outside consultant expenses for sales and marketing activities in preparation for U.S. commercialization, and a $1.2 million increase in legal fees associated with increased intellectual property development and protection. The remaining year over year increase was primarily related to higher expenses due to becoming a public company.

Interest expense, net. Interest expense, net remained consistent at $0.5 million for the year ended December 31, 2016 and 2015.

Comparison of years ended December 31, 2015 and 2014

Total revenue. Total revenue increased by $0.5 million to $4.0 million during the year ended December 31, 2015, compared to $3.5 million during the year ended December 31, 2014. This increase was attributable to a $2.0 million increase in revenue, related party due to the increased volume sold in the Middle Eastern market during the year ended December 31, 2015 as a result of our distributor selling to new territories, offset by a $1.5 million decrease in revenue, as we discontinued sales in Europe and Mexico beginning in the third quarter of 2015 and the volume sold in those regions decreased substantially.

Cost of revenue. Cost of revenue decreased by $0.4 million to $2.5 million during the year ended December 31, 2015, compared to $2.9 million during the year ended December 31, 2014. This decrease was primarily attributable to lower payroll and outside consulting expense associated with manufacturing our products. During the year ended December 31, 2015, we operated with a lower engineering and supervisory headcount in our manufacturing department compared to the year ended December 31, 2014.

Research and development expenses. R&D expenses increased $7.2 million to $13.0 million during the year ended December 31, 2015, compared to $5.8 million during the year ended December 31, 2014. This increase was primarily attributable to the initiation of our SMART trial in April 2015.

Selling, general and administrative expenses. SG&A expenses decreased $1.2 million to $3.5 million during the year ended December 31, 2015, compared to $4.7 million during the year ended December 31, 2014. This decrease was primarily attributable to decreases in selling and marketing expenses due to the discontinuation of sales in Mexico and Europe beginning in the third quarter of 2015.

Interest expense, net. Interest expense, net increased $0.3 million to $0.5 million during the year ended December 31, 2015, compared to an expense of $0.2 million during the year ended December 31, 2014. The increase in interest expense was attributable to an increase in outstanding debt to support our operations during the year ended December 31, 2015 as compared to the year ended December 31, 2014.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2016, we had cash and cash equivalents and short-term investments of $75.5 million and an accumulated deficit of $76.6 million. Our primary sources of capital have been the sale of common stock in our IPO, private placements of preferred stock and the incurrence of debt. On October 5, 2016, our Registration Statement on Form S-1 relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 5,000,000 shares of our common stock at a price of $15.00 per share for aggregate cash proceeds of approximately $67.2 million, net of underwriting discounts, commissions, and offering costs. The IPO closed on October 12, 2016. In addition, we have raised an aggregate of $70.5 million in proceeds from convertible preferred stock financings. Furthermore, we have $10.0 million in debt with Pacific Western Bank (as successor in interest to Square 1 Bank) that was amended in September and December 2016 and allows us to borrow an additional $5.0 million through December 2017. As of December 31, 2016, our aggregate outstanding indebtedness under the loan and security agreement was $10.0 million.

We expect to incur substantial additional expenditures in the next 12 months to support the commercial launch of our product in the United States. We believe that our existing cash and cash equivalents and short-term investments and expected revenue, will be sufficient to meet our capital requirements and fund our operations through the next two years. We expect our costs and expenses to increase in the future as we continue U.S. commercialization of our Obalon balloon system, including support of a direct sales force and the expansion of our manufacturing facilities, and as we continue to make substantial expenditures on research and development, including for conducting clinical trials of our products in development. Additionally, we expect to incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the costs and expenses of maintaining and growing our U.S. sales and marketing infrastructure and our manufacturing operations;
- the degree of success we experience in commercializing our Obalon balloon system;
- the revenue generated by sales of our Obalon balloon system and 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 developing variations of our Obalon balloon system, and, if necessary, obtaining FDA approval of such variations;
- the emergence of competing or complementary technological developments;

- the extent to which our Obalon balloon system is adopted by the physician community;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Additional financing, if necessary, may not be available on a timely basis on terms acceptable to us, or at all. We may raise funds in equity or debt financings 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. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment or expansion of sales and marketing capabilities or other activities necessary to commercialize our products.

Loan and security agreement

In June 2013, we entered into a $3.0 million loan and security agreement with Square 1 Bank (predecessor in interest to Pacific Western Bank), which we subsequently amended in October 2014, September 2016 and December 2016.

As of December 31, 2016, we could borrow up to $15.0 million in two tranches as follows: a first tranche consisting of $10.0 million which was carried over from our previous agreement in September 2016, and a second tranche of $5.0 million which may be drawn by us any time prior to December 21, 2017. As of December 31, 2016, we have not drawn down on this second tranche, and had $10.0 million outstanding under this loan and security agreement. The outstanding debt has a variable annual interest rate equal to the greater of the prime rate plus 1.50% or 5.0%, and matures in December 2020.

The loan and security agreement provides for an interest-only period through June 21, 2018, followed by a 30-month principal and interest period. Pursuant to the loan and security agreement, we provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property, owned by us.

The loan and security agreement provides for restrictions on, among other things, our ability to incur additional indebtedness, change the name or location of our business, change our business, merge with or acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with our affiliates, create liens, sell assets, pay any subordinated debt, and store certain inventory and equipment with third parties. In addition, the loan and security agreement also requires that the Company's accounts maintained with the bank contain an aggregate balance in an amount equal to or greater than the total amount of outstanding debt under the loan and security agreement.

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,		
	2016	2015	2014
Net cash (used in) provided by:			
Operating activities	$ (19,368)	$ (11,392)	$ (9,907)
Investing activities	6,201	2,777	(7,918)
Financing activities	82,786	5,062	22,188
Exchange rate effect	—	7	12
Net increase (decrease) in cash and cash equivalents	$ 69,619	$ (3,546)	$ 4,375

Net cash used in operating activities

During the year ended December 31, 2016, net cash used in operating activities was $19.4 million, consisting primarily of a net loss of $20.5 million and a decrease in net operating assets of $0.3 million. These items were partially offset by non-cash charges of $1.4 million, consisting primarily of changes in the fair value of warrant liability, stock-based compensation expense, depreciation and non-cash interest expense related to amortization of investment premium and debt discount.

During the year ended December 31, 2015, net cash used in operating activities was $11.4 million, consisting primarily of a net loss of $15.6 million, offset by a decrease in net operating assets of $3.4 million and non-cash charges of $0.8 million. The decrease in net operating assets primarily consisted of increased accrued expenses for our SMART trial and a customer deposit received from Bader. The non-cash charges consisted primarily of depreciation, stock-based compensation, and non-cash interest expense related to amortization of investment premium and debt discount.

During the year ended December 31, 2014, net cash used in operating activities was $9.9 million, consisting primarily of a net loss of $9.9 million and an increase in net operating assets of $0.3 million, partially offset by non-cash charges of $0.3 million. The increase in net operating assets was primarily attributable to increases in inventory and other current assets and decreases in accrued clinical expenses. The non-cash charges primarily consisted of depreciation, stock-based compensation expense and non-cash interest expense related to amortization of investment premium and debt discount.

Net cash provided by (used in) investing activities

During the year ended December 31, 2016, net cash provided by investing activities was $6.2 million, consisting primarily of maturities of short-term investments, partially offset by purchases of short term investments.

During the year ended December 31, 2015, net cash provided by investing activities was $2.8 million, consisting primarily of maturities of short-term investments, partially offset by purchases of short term investments.

During the year ended December 31, 2014, net cash used in investing activities was $7.9 million, consisting primarily of purchases of short-term investments, partially offset by maturities of short-term investments.

Net cash provided by financing activities

During the year ended December 31, 2016, net cash provided by financing activities was $82.8 million, consisting of net proceeds of $67.2 million from our IPO, net proceeds of $14.5 million from the issuance of Series E convertible preferred stock and proceeds of $1.1 million from sale of common stock upon exercise of stock options.

During the year ended December 31, 2015, net cash provided by financing activities was $5.1 million, consisting primarily of proceeds of $5.0 million from borrowings under our loan and security agreement with Pacific Western Bank.

During the year ended December 31, 2014, net cash provided by financing activities was $22.2 million, consisting primarily of net proceeds of $20.2 million from the issuance of Series D convertible preferred stock and a $2.0 million increase in borrowings under our loan and security agreement with Pacific Western Bank.

OFF-BALANCE SHEET ARRANGEMENTS

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

CONTRACTUAL OBLIGATIONS

Our principal obligations consist of the operating lease for our facility and our loan and security agreement with Pacific Western Bank. The following table sets out, as of December 31, 2016, our contractual obligations due by period:

	Payments due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations(1).	$ 745	$ 248	497	$ —	$ —
Term loan	10,000	—	6,000	4,000	—
Total	$ 10,745	$ 248	$ 6,497	$ 4,000	$ —

(1) Consists of obligations under a multi-year, non-cancelable building lease for our facility in Carlsbad, California. An amendment to the lease was executed in February 2017 and is reflected herein. The lease will expire on March 31, 2019.

We enter 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 and not included in the table above. As of December 31, 2016, we had completed our lead clinical trial and all material expenses were accrued.

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 Financial Statements-Note 2-Recent Accounting Pronouncements" of our annual financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

INTEREST RATE RISK

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, short-term investments, and long term debt. All of our cash equivalents and short-term investments are carried at quoted market prices. All of our short-term investments are U.S. treasury notes with maturities of less than one year. Due to the short-term maturities and low risk profile of our cash equivalents and short-term investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our cash equivalents. We do not currently use or plan to use financial derivatives in our investment portfolio.

In addition, we have outstanding debt under our loan and security agreement with Pacific Western Bank that bears interest. As of December 31, 2016, our aggregate outstanding indebtedness was $10.0 million, which bears interest at the rate equal to the greater of the prime rate plus 1.50% or 5.0%. We do not believe an immediate 10% increase in interest rates would have a material effect on interest expense for the loan with Pacific Western Bank, and therefore we do not expect our operating results or cash flows to be materially affected to any degree by a sudden change in market interest rates.

CREDIT RISK

As of December 31, 2016 and 2015, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

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, 2016, 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

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC, which requires such assessment to be included beginning with a registrant's second Annual Report on Form 10-K.

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, 2016 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 2017 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 2017 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 2017 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 2017 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 2017 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

We have filed the following documents as part of this Annual Report:

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Obalon Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Obalon Therapeutics, Inc. and subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2016. 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 conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Obalon Therapeutics, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

San Diego, California
February 23, 2017

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

	December 31,	
	2016	**2015**
Assets		
Current assets:		
Cash and cash equivalents	$ 72,975	$ 3,356
Short-term investments	2,500	9,175
Accounts receivable, related party	515	636
Inventory	827	363
Other current assets	1,244	273
Total current assets	78,061	13,803
Property and equipment, net	717	418
Total assets	$ 78,778	$ 14,221
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 595	$ 549
Accrued compensation	2,497	1,250
Accrued clinical expenses	101	913
Other current liabilities	1,399	493
Customer deposit from related party	—	1,283
Current portion of long-term loan	—	747
Warrant liability	—	332
Total current liabilities	4,592	5,567
Long-term loan, excluding current portion	9,881	9,094
Total liabilities	14,473	14,661
Commitments and contingencies (See Note 10)		
Convertible preferred stock		
Series A convertible preferred stock, $0.001 par value; 2,333,332 shares authorized; none and 804,595 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively; liquidation preference of $0 and $7,000 at December 31, 2016 and December 31, 2015, respectively	—	6,773
Series B convertible preferred stock, $0.001 par value; 4,333,332 shares authorized; none and 1,494,248 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively; liquidation preference of $0 and $6,500 at December 31, 2016 and December 31, 2015	—	6,454
Series C convertible preferred stock, $0.001 par value; none and 7,809,939 shares authorized at December 31, 2016 and December 31, 2015, respectively; none and 2,668,533 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively; liquidation preference of $0 and $16,523 at December 31, 2016 and December 31, 2015, respectively	—	16,393
Series C-1 convertible preferred stock, $0.001 par value; none and 2,783,334 and shares authorized at December 31, 2016 and December 31, 2015, respectively; none and 480,286 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively; liquidation preference of $0 and $5,000 at December 31, 2016 and December 31, 2015, respectively	—	4,984
Series D convertible preferred stock, $0.001 par value; none and 11,546,013 shares authorized at December 31, 2016 and December 31, 2015, respectively; none and 2,732,552 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively; liquidation preference of $0 and $41,180 at December 31, 2016 and December 31, 2015, respectively	—	20,095

Series E convertible preferred stock, $0.001 par value; 0 shares authorized at December 31, 2016 and 2015, respectively; 0 shares issued and outstanding at December 31, 2016 and 2015, respectively; liquidation preference of $0 at December 31, 2016 and 2015, respectively	—	—
	—	54,699
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 300,000,000 and 35,000,000 shares authorized at December 31, 2016 and December 31, 2015, respectively; 16,773,205 and 575,126 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	17	1
Additional paid-in capital	140,898	1,002
Accumulated other comprehensive loss	(1)	—
Accumulated deficit	(76,609)	(56,142)
Total stockholders' equity (deficit)	64,305	(55,139)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 78,778	$ 14,221

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,		
	2016	2015	2014
Revenue:			
Revenue	$ —	$ 216	$ 1,683
Revenue, related party	3,393	3,823	1,856
Total revenue	3,393	4,039	3,539
Cost of revenue	2,809	2,503	2,912
Gross profit	584	1,536	627
Operating expenses:			
Research and development	9,872	12,978	5,767
Selling, general and administrative	10,217	3,491	4,700
Total operating expenses	20,089	16,469	10,467
Loss from operations	(19,505)	(14,933)	(9,840)
Interest expense, net	(477)	(549)	(220)
(Loss) gain from change in fair value of warrant liability	(466)	(34)	167
Other (expense) income, net	(19)	(41)	3
Net loss	(20,467)	(15,557)	(9,890)
Other comprehensive (loss) income	(1)	5	9
Net loss and comprehensive loss	$ (20,468)	$ (15,552)	$ (9,881)
Net loss per share, basic and diluted	$ (4.85)	$ (27.14)	$ (18.61)
Weighted-average common shares outstanding, basic and diluted	4,221,893	573,181	531,430

See accompanying notes to consolidated financial statements.

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

	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series C-1 convertible preferred stock		Series D convertible preferred stock		Series E convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2013	804,595	$ 6,773	1,494,248	$ 6,454	2,668,533	$ 16,393	480,286	$ 4,984	—	$ —	—	$ —	529,199	$ 1	$ 540	$ (14)	$ (30,695)	$ (30,168)
Issuance of common stock for cash	—	—	—	—	—	—	—	—	—	—	—	—	4,285	—	8	—	—	8
Issuance of preferred stock at $7.5351 per share, net of issuance costs of $368	—	—	—	—	—	—	—	—	2,732,552	20,222	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	185	—	—	185
Foreign currency translation adjustment and other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	9	—	9
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(9,890)	(9,890)
Balance at December 31, 2014	804,595	$ 6,773	1,494,248	$ 6,454	2,668,533	$ 16,393	480,286	$ 4,984	2,732,552	$ 20,222	—	$ —	533,484	$ 1	$ 733	$ (5)	$ (40,585)	$ (39,856)
Issuance of common stock for cash	—	—	—	—	—	—	—	—	—	—	—	—	41,642	—	62	—	—	62
Issuance of warrants in connection with preferred stock financing	—	—	—	—	—	—	—	—	—	(127)	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	207	—	—	207
Foreign currency translation adjustment and other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(15,557)	(15,557)
Balance at December 31, 2015	804,595	$ 6,773	1,494,248	$ 6,454	2,668,533	$ 16,393	480,286	$ 4,984	2,732,552	$ 20,095	—	$ —	575,126	$ 1	$ 1,002	—	$ (56,142)	$ (55,139)
Issuance of common stock for cash upon exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	808,885	1	819	—	—	820
Issuance of preferred stock at $8.2932 per share, net of issuance costs of $94	—	—	—	—	—	—	—	—	—	—	1,916,425	15,799	—	—	—	—	—	—

Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	563	—	—	563
Conversion of preferred stock to common stock in connection with initial public offering	(804,595)	(6,773)	(1,494,248)	(6,454)	(2,668,533)	(16,393)	(480,286)	(4,984)	(2,732,552)	(20,095)	(1,916,425)	(15,799)	10,360,419	10	70,488	—	—	70,498
Issuance of common stock in initial public offering, net of underwriting discount, commissions and issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	5,000,000	5	67,228	—	—	67,233
Net exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	28,775	—	591	—	—	591
Reclassification of warrant liability as equity	—	—	—	—	—	—	—	—	—	—	—	—	—	—	207	—	—	207
Foreign currency translation adjustment and other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(20,467)	(20,467)
Balance at December 31, 2016	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	16,773,205	$ 17	$ 140,898	$ (1)	$ (76,609)	$ 64,305

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,		
	2016	**2015**	**2014**
Operating activities:			
Net loss	$ (20,467)	$ (15,557)	$ (9,890)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	192	167	166
Stock-based compensation	563	207	185
Loss on disposal of fixed assets	13	19	5
Change in fair value of warrant liability	466	34	(167)
Amortization of investment premium, net	125	260	64
Amortization of debt discount	70	79	41
Change in operating assets and liabilities:			
Accounts receivable, net	—	96	83
Accounts receivable from related party	121	(481)	4
Inventory	(464)	77	(166)
Other current assets	(985)	27	(109)
Accounts payable and accrued expenses	46	370	(33)
Accrued compensation	1,247	1,018	33
Accrued clinical expenses	(812)	898	(129)
Other current liabilities	517	111	6
Customer deposit from related party	—	1,283	—
Net cash used in operating activities	(19,368)	(11,392)	(9,907)
Investing activities:			
Purchases of short-term investments	(18,897)	(18,590)	(12,400)
Maturities of short-term investments	25,450	21,500	4,250
Sales of short-term investments	—	—	500
Purchase of property and equipment	(352)	(139)	(268)
Proceeds from disposal of property and equipment	—	6	—
Net cash provided by (used in) investing activities	6,201	2,777	(7,918)
Financing activities:			
Issuance of preferred stock for cash, net of offering costs	14,517	—	13,622
Issuance of preferred stock to related party for cash	—	—	6,600
Proceeds from initial public offering, net of issuance costs	67,233	—	—
Proceeds from long-term loan, net of issuance costs	—	5,000	4,958
Fees paid in connection with loan amendment	(30)	—	—
Repayments of long-term loans	—	—	(3,000)
Sale of common stock upon exercise of stock options	1,066	62	8
Net cash provided by financing activities	82,786	5,062	22,188
Effect of exchange rate changes on cash and cash equivalents	—	7	12
Net increase (decrease) in cash and cash equivalents	69,619	(3,546)	4,375
Cash and cash equivalents at beginning of period	3,356	6,902	2,527
Cash and cash equivalents at end of period	$ 72,975	$ 3,356	$ 6,902
Supplemental cash flow information:			
Interest paid	$ 527	$ 475	$ 164
Income taxes paid	$ —	$ 2	$ 1
Conversion of convertible preferred stock to common stock	$ 70,498	$ —	$ —
Net exercises of warrants	$ 591	$ —	$ —
Conversion of customer deposit from related party to preferred stock	$ 1,283	$ —	$ —
Property and equipment in accounts payable	$ 140	$ —	$ —

See accompanying notes to consolidated financial statements.

1. Organization and Basis of Presentation

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 obese and overweight people. Using its patented technology, the Company has developed the Obalon balloon system, the first and only FDA approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients.

The consolidated financial statements include the accounts of Obalon Therapeutics, Inc., and its wholly owned subsidiaries, Obalon Italy SRL and Obalon Therapeutics, LLC. Obalon Therapeutics, LLC is a shell Company, which owns 99% of Obalon Mexico DE RL CV. Obalon Italy SRL was dissolved during 2015 and Obalon Mexico DE RL CV was dissolved during 2016. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The Company's principal operations are located in Carlsbad, California and it operates in one business segment.

As of December 31, 2016, the Company has devoted a substantial portion of its efforts to product development, raising capital, and building infrastructure. 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 revenue, including revenue from related parties, of $3.4 million, $4.0 million and $3.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. However, the Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and has funded its activities to date almost exclusively from debt and equity financings. On September 8, 2016, the Company received premarket approval from the U.S. Food and Drug Administration, or FDA, to market the Obalon balloon system for temporary use to facilitate weight loss in obese adults with a body mass index, or 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. For all periods presented, all sales are to customers outside of the United States.

Initial Public Offering

On October 5, 2016, the Company's Registration Statement on Form S-1 (File No. 333-213551) relating to the initial public offering, or IPO, of its common stock was declared effective by the Securities and Exchange Commission, or SEC. Pursuant to such Registration Statement, the Company sold an aggregate of 5,000,000 shares of its common stock at a price of $15.00 per share for aggregate cash proceeds of approximately $67.2 million, net of underwriting discounts, commissions, and offering costs. The IPO closed on October 12, 2016.

On October 12, 2016, immediately prior to the closing of the IPO, the following events occurred:

- An aggregate of 10,360,419 shares of common stock, excluding any warrant conversions, were issued to the holders of the Company's Series A, Series B, Series C, Series C-1, Series D and Series E convertible preferred stockholders upon the automatic conversion of all shares of convertible preferred stock to common stock. As a result, no Series A, Series B, Series C, Series C-1, Series D or Series E convertible preferred stock remain outstanding at December 31, 2016.
- Initiated on October 11, 2016, Series C-1 and D warrants for 36,562 shares of the Company's preferred stock were exercised by Pacific Western Bank (as successor in interest to Square 1 Bank) via cashless exercise resulting in the subsequent issuance of 16,558 shares of common stock on October 12, 2016.
- Series D warrants for 24,550 shares of the Company's preferred stock were automatically net exercised resulting in the issuance of 12,217 shares of common stock.
- The remaining outstanding Series C preferred stock warrants exercisable for an aggregate of 24,224 shares of convertible preferred stock automatically converted into warrants exercisable for an aggregate of 24,224 shares of common stock.
- The 2016 Plan, and the 2016 ESPP, as described in Note 7, were adopted.

- An aggregate of 223,371 shares of common stock reserved but not issued under the 2008 Plan became available for grant under the 2016 Plan.
- The Company filed its amended and restated certificate of incorporation on October 12, 2016, authorizing 300,000,000 shares of common stock and 10,000,000 shares of preferred stock.

February 2014 Reverse Stock Split

In February 2014, the board of directors of the Company approved a 3-for-1 reverse stock split of the Company's common and preferred stock. All share and per share information included in the accompanying consolidated financial statements and notes to consolidated financial statements give retroactive effect to this reverse stock split for the Company's common and preferred stock.

September 2016 Reverse Stock Split

In September 2016, the Company's board of directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a reverse stock split of the Company's issued and outstanding common stock and convertible preferred stock at a 2.9-to-1 ratio, which was effected on September 23, 2016. All share and per share information included in the accompanying consolidated financial statements and notes to the consolidated financial statements have been retroactively adjusted to reflect the reverse stock split for the Company's common and preferred stock for all periods presented.

Liquidity

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, 2016, its accumulated deficit was $76.6 million. Since inception, the Company has financed its operations primarily through private placements of preferred securities, the sale of common stock through its IPO and, to a lesser extent, debt financing arrangements. The Company expects to continue to incur net losses for the foreseeable future as it builds its sales and marketing organization, supports commercialization of its product in the United States and continues research and development efforts. 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. The Company believes that its existing cash and cash equivalents and short-term investments and expected revenue will be sufficient to meet its capital requirements and fund its operations through the next two years.

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, 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.

Short-Term Investments

The Company classifies its investments as available-for-sale and records such assets at estimated fair value on the balance sheet, with unrealized gains and losses, if any, reported as a component of other comprehensive loss within the consolidated statements of operations and comprehensive loss. All of the Company's short-term investments are U.S. Treasury notes with maturities of less than one year. For the years ended December 31, 2016, 2015 and 2014, unrealized losses were immaterial amounts, respectively. Realized gains and losses would be calculated on the specific-identification method and recorded as interest income. There have been no material realized gains and losses for the years ended December 31, 2016, 2015 and 2014. The Company periodically reviews available-for-sale securities for other-than-temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable.

Fair Value Measurements

The carrying values of the Company's financial instruments, including cash and cash equivalents, accounts receivable from related party, 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 is 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 at both December 31, 2016 and 2015, 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 distributors. 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,		
	2016	2015	2014
Single largest customer:			
Revenue, related party	100.0 %	94.7 %	52.4%
Accounts receivable, related party	100.0 %	100.0 %	61.0%
Second largest customer:			
Revenue	N/A	N/A	10.0%
Accounts receivable	N/A	N/A	2.6%

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

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, 2016, 2015 and 2014.

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 uses the estimated 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, including stock options, are recorded at fair value as of the grant date using the Black-Scholes option pricing model and recognized as expense on a straight-line basis over the employee's or director's requisite service period (generally the vesting period). 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

Revenue relates to sales of components of the Obalon balloon system, which includes the balloon and accessory kit, EzFill inflation system, pre-filled can of gas and placebo capsule.

The Company recognizes revenue when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred, (iii) the selling price is fixed or determinable and (iv) collectability is reasonably assured. Determination of criteria (iii) and (iv) are based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectability of those amounts. The Company does not provide for rights of return to customers on product sales, with the exception of products that fail to conform to the Company's specifications. As these non-conforming returns have historically been immaterial, the Company does not record a provision for returns. The Company does not have any post shipment obligations or acceptance provisions within its customer contracts. The Company occasionally offers discounts off its standard prices to non-distributor customers, which are agreed upon and known at the time of sale. In these cases, revenue is recognized net of these discounts. Shipping charges billed to customers are included in product revenue and the related shipping costs are included in cost of revenue.

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, 2016, 2015 and 2014 was immaterial for each year.

Advertising Costs

Advertising costs are expensed as incurred and included in selling, general and administrative expense. Advertising costs for the years ended December 31, 2016, 2015 and 2014 were approximately $0.9 million, $0.3 million and $0.3 million for 2016, 2015 and 2014, respectively.

Preferred Stock Warrants

The fair value of preferred stock warrants issued in conjunction with debt issuances was initially recorded as a warrant liability and debt discount. The debt discount associated with the initial warrant fair value is being amortized to interest expense using the effective-interest method in the Company's consolidated statements of operations and comprehensive loss over the term of the debt.

The fair value of preferred stock warrants issued in conjunction with preferred stock issuances was initially recorded as a warrant liability and reduction of the proceeds received. The fair value of the warrants was estimated using the Black-Scholes option pricing model based on the estimated fair value of the preferred stock at the valuation date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying preferred stock. Prior to the automatic conversion of the warrants in conjunction with the IPO on October 12, 2016, the warrant liability was remeasured each reporting period with changes in fair value being recognized in the consolidated statements of operations and comprehensive loss.

As noted above in Note 1, in connection with the completion of the Company's IPO, all the remaining outstanding warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock. As such, the Company reclassified the remaining warrant liability to stockholders' equity as the converted warrants met the definition of an equity instrument under derivative accounting guidance. The Company performed the final remeasurement of the warrant liability as of the IPO closing date. See Note 3 for the amounts associated with the fair value remeasurements and Note 8 for further description of the remaining warrants.

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.

Dilutive common stock equivalents are comprised of convertible preferred stock, warrants and unexercised stock options outstanding under the Company's equity plan.

Recent Accounting Pronouncements

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

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* ASU 2014-15 requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable that when, considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, for both annual and interim periods. ASU 2014-15 also requires certain disclosures around management's plans and evaluation, as well as the plans, if any, that are intended to mitigate those conditions or events that will alleviate the substantial doubt. ASU 2014-15 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016. The adoption of ASU 2014-15 did not have a material impact on the Company's consolidated financial statements.

In July 2015, FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*. This update applies to companies that measure inventory on a first in, first out, or FIFO, or average cost basis. Under this update, companies are to measure their inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion. The amendments in this update are effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016 with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of ASU 2015-11 did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*. 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. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements.

In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers*, which defers the effective date of ASU 2014-09 for all entities by one year. ASU 2014-09, which was issued in March 2014 and has been codified with the Accounting Standards Codification as Topic 606, is now effective for public companies for annual reporting periods beginning after December 15, 2017, including interim periods within those reporting periods. ASC 606 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including

industry-specific guidance. In addition, ASC 606 provides guidance on accounting for certain revenue-related costs including, but not limited to, when to capitalize costs associated with obtaining and fulfilling a contract. ASC 606 provides companies with two implementation methods: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. Since ASU 2014-09 was issued, several additional ASUs have been issued and incorporated within ASC 606 to clarify various elements of the guidance. While the Company is continuing to assess all potential impacts of the standard, they do not believe that their current revenue streams will be materially affected. As the Company begins commercialization in the U.S. during 2017 and enters into sales agreements with customers as part of this commercialization, the Company will continue to assess the potential impacts of the standard, including the impact to the pattern with which they recognize revenue based on the terms entered into and finalizing the determination of transition approach.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which involves several aspects of the accounting for stock-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This new guidance will require all income tax effects of awards to be recognized as income tax expense or benefit in the income statement when the awards vest or are settled, as opposed to additional paid-in-capital where it is currently recorded. It also will allow an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting. All tax-related cash flows resulting from stock-based payments are to be reported as operating activities on the statement of cash flows. The guidance also allows a Company to make a policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. This new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016, with early adoption permitted. The Company does not recognize any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on its deferred tax assets. The Company does not anticipate the adoption of this standard will have a material impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which addresses the following eight specific cash flow issues: Debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies (including bank-owned life insurance policies); distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2017, with early adoption permitted. The Company does not anticipate that the adoption of ASU 2016-15 will have a material impact 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, 2016 and 2015 are as follows (in thousands):

		Fair value measurements at reporting date using		
	Balance as of December 31, 2016	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Short-term investments:				
U.S. Treasury bonds(2)	$ 2,500	$ 2,500	$ —	$ —
Total assets	$ 2,500	$ 2,500	$ —	$ —

	Balance as of December 31, 2015	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:				
Money market funds(1)	$ 3,593	$ 3,593	$ —	$ —
U.S. Treasury bonds(2)	9,175	9,175	—	—
Total assets	$ 12,768	$ 12,768	$ —	$ —
Liabilities:				
Warrant liability	$ 332	$ —	$ —	$ 332
Total liabilities	$ 332	$ —	$ —	$ 332

(1) Classified as cash and cash equivalents on the consolidated balance sheets.
(2) Classified as short-term investments on the consolidated balance sheets.

The Company's investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as of December 31, 2016 and 2015.

As discussed in Note 2 above, 61,112 warrants were exercised to common stock and all of the remaining outstanding 24,224 warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock in connection with the IPO and are equity classified at December 31, 2016. Prior to the exercise and the conversion, the Company estimated the fair value of convertible preferred stock warrants at the time of issuance and subsequent remeasurements using the Black-Scholes option-pricing model at each reporting date.

The following assumptions were used in the Black-Scholes option-pricing model to determine the fair value of the convertible preferred stock warrants at the exercise and conversion date, and December 31, 2015:

	October 12, 2016	December 31, 2015
Assumed risk-free interest rate	0.90% - 1.64%	1.28% - 2.06%
Assumed volatility	53.42% - 62.36%	66.76% - 70.66%
Expected life	2.40 yrs - 7.96 yrs	3.15 - 8.75 yrs
Expected dividend yield	—%	—%
Preferred stock fair value:		
Series D	$13.92	$8.41
Series C-1	$13.92	$2.24
Series C	$13.92	$1.72

The assumptions were determined as follows:

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

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

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

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

Preferred stock fair value — On October 12, 2016, the conversion date, the Company used the closing price of its common stock. Given the absence of a public trading market on December 31, 2015, the Company considered numerous objective and subjective factors to determine the fair value of preferred stock at each valuation date. These factors included, but were not limited to, (i) contemporaneous valuations of preferred stock performed by unrelated third-party specialists; (ii) the prices for preferred stock sold

to outside investors; (iii) the rights, preferences and privileges of preferred stock relative to common stock; (iv) developments in the business; and (v) the likelihood of achieving a liquidity event, such as an IPO or a merger or acquisition of the Company, given prevailing market conditions.

As of December 31, 2015, reasonable changes in the unobservable inputs would not be expected to have a significant impact on the consolidated financial statements. The Company's policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no significant transfers into or out of Level 1, 2, or 3 for the years ended December 31, 2016 and 2015.

The following table provides reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) for the years ended December 31, 2016 and 2015 (in thousands):

	Fair value measurements at reporting date using significant unobservable inputs (Level 3)
Balance at December 31, 2014	$ 56
Issuance of warrants for the purchase of convertible preferred stock	242
Loss from change in fair value of warrant liability	34
Balance at December 31, 2015	332
Loss from change in fair value of warrant liability	466
Fair value of warrants exercised	(591)
Reclassification of warrants to stockholders' equity (deficit)	(207)
Balance at December 31, 2016	$ —

Instruments Not Recorded at Fair Value on a Recurring Basis

The estimated fair value of long-term loan is determined by Level 2 inputs and is based primarily on quoted market prices for the same or similar issues. The recorded value of long-term loan approximates the current fair value due to the proximity of when the long-term loan was negotiated.

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,		
	2016	2015	2014
Net loss	$ (20,467)	$ (15,557)	$ (9,890)
Weighted-average shares used in computing net loss per share	4,221,893	573,181	531,430
Net loss per share, basic and diluted	$ (4.85)	$ (27.14)	$ (18.61)

The following table sets forth the outstanding potentially dilutive securities determined using the treasury stock and if-converted methods 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,		
	2016	2015	2014
Convertible preferred stock, on an as-converted basis	—	8,443,994	6,654,734
Stock options to purchase common stock	830,145	—	59,438
Total	830,145	8,443,994	6,714,172

5. Balance Sheet Details

Short-term investments consist of the following (in thousands):

	Maturity (in years)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
At December 31, 2016:					
U.S. Treasury	1 year or less	$ 2,501	$ —	$ (1)	$ 2,500

	Maturity (in years)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
At December 31, 2015:					
U.S. Treasury	1 year or less	$ 9,178	$ —	$ (3)	$ 9,175

Inventory consist of the following (in thousands):

	December 31,	
	2016	2015
Raw materials	$ 379	$ 235
Work in process	239	121
Finished goods	209	7
Total	$ 827	$ 363

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

	December 31,	
	2016	2015
Prepaid assets	$ 962	$ 234
Interest receivable	5	25
Other assets	277	14
Total	$ 1,244	$ 273

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

	December 31,	
	2016	2015
Computer equipment	$ 334	$ 255
Leasehold improvements	193	181
Furniture and fixtures	118	82
Scientific equipment	854	770
Construction in progress, or CIP	302	24
	1,801	1,312
Less: accumulated depreciation and amortization	(1,084)	(894)
Total	$ 717	$ 418

Depreciation and amortization expense for the years ended December 31, 2016, 2015 and 2014 was $0.2 million for all periods, respectively.

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

	December 31,	
	2016	2015
Accrued legal	$ 53	$ 162
Accrued professional fees	560	195
Accrued interest	44	44
Other accrued expenses	742	92
Total	$ 1,399	$ 493

6. Term Loan

In June 2013, the Company entered into a loan and security agreement, or 2013 Loan Agreement, with Pacific Western Bank (as successor in interest to Square 1 Bank) allowing for borrowings up to $3.0 million. In addition to the interest payments, Pacific Western Bank received warrants for the purchase of up to 8,693 shares of the Company's Series C-1 convertible preferred stock. On October 11, 2016, all the warrants were net exercised into 2,689 shares which were subsequently issued as common stock on October 12, 2016 in conjunction with the IPO closing. In October 2014, the Company amended the 2013 Loan Agreement and executed a $10.0 million credit facility with Pacific Western Bank, or 2014 Loan Agreement. The 2014 Loan Agreement was separated into two tranches, Term Loan A and Term Loan B. Term Loan A was $5.0 million, which included the existing $3.0 million of outstanding debt and the additional $2.0 million that was funded upon closing of the 2014 Loan Agreement. Term Loan B was $5.0 million and was available upon receipt of at least $20.0 million in proceeds from the issuance and sale of the Company's equity securities to investors. Term Loan B was funded after the close of the Company's Series D financing in January 2015. As part of the 2014 Loan Agreement, the Company issued Pacific Western Bank additional warrants to purchase up to 27,869 shares of its Series D convertible preferred stock at $7.5351 per share. On October 11, 2016, all the warrants were net exercised into 13,869 shares which were subsequently issued as common stock on October 12, 2016 in conjunction with the IPO closing. As of December 31, 2016, Pacific Western Bank held 16,558 shares of common stock associated with its warrant exercises and had no warrants outstanding.

The present value of the future cash flows under the 2014 Loan Agreement terms did not exceed the present value of the future cash flows under the 2013 Loan Agreement terms by more than 10%. As such, the Company treated this amendment as a modification and recorded the associated immaterial facility fee and the associated immaterial fair value of the warrants as a discount to the 2014 Loan Agreement. This discount and the remaining balance of debt issuance costs and debt discount of the 2013 Loan Agreement were amortized to interest expense over the remaining term of the 2014 Loan Agreement using the effective-interest method.

On September 7, 2016, the Company entered into the September 2016 Loan Agreement, with Pacific Western Bank, which amended the existing outstanding debt agreement described above. The September 2016 Loan Agreement allows for total borrowings up to $15.0 million in two tranches as follows: a first tranche consisting of $10.0 million funded on September 7, 2016, of which the full $10.0 million must 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 consisting of an additional $5.0 million which may be drawn at any time prior to March 7, 2017. The first tranche and the second tranche are collectively referred to as the "Term Loans." The Term Loans bear interest at the greater of prime rate plus 1.50% per annum, or 5.00%. The Term Loans mature on September 7, 2020 and have an interest-only period through March 2018 followed by 30 equal monthly installments of principal and interest. The Term Loans may be prepaid in full at any time with no additional cost.

Pursuant to the September 2016 Loan Agreement, the Company issued to Pacific Western Bank a warrant to purchase a number of the Company's Series E Preferred Stock, at a purchase price of $8.2932 per share, equal to 3.0% of the total amount of up to $5.0 million of debt drawn over $10.0 million divided by the purchase price, which automatically converted into a warrant to purchase the same number of shares of common stock immediately prior to the closing of the Company's IPO, and will only be exercisable in the event that the Company borrows all or part of the second tranche. As the Company had not drawn down on the second tranche, none of these warrants were exercisable.

On December 21, 2016, the Company entered into the December 2016 Loan Agreement with Pacific Western Bank, which further amended the existing outstanding debt agreements described above. The December 2016 Loan Agreement kept total borrowings consistent of up to $15.0 million in two tranches as follows: a first tranche consisting of $10.0 million funded on December 21, 2016, of which the full $10.0 million must 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 consisting of an additional $5.0 million which may be drawn at any time prior to December 21, 2017. The Term Loans bear interest at the greater of prime rate plus 1.50% per annum, or 5.00%. The Term Loans mature on December 21, 2020 and have an interest-only period through June 21, 2018 followed by 30 equal monthly installments of principal

and interest. The Term Loans may be prepaid in full at any time with no additional cost. The Series E warrant issued with the 2016 Loan Agreement was canceled without exercise in conjunction with the amendment.

The present value of the future cash flows under the 2016 Loan Agreement and the December 2016 Loan Amendment did not exceed the present value of the future cash flows under the predecessor terms by more than 10%. As such, the Company treated the amendments as modifications and recorded the associated immaterial facility fees as a discount to the amended debt. This discount and the remaining balance of debt issuance costs and debt discount are amortized to interest expense over the remaining term of the December 2016 Loan Agreement using the effective-interest method.

The December 2016 Loan Agreement also requires that the Company's accounts maintained with the bank contain an aggregate balance in an amount equal to or greater than the total amount of outstanding debt under the December 2016 Loan Agreement.

Total long-term loan and unamortized debt discount balances are as follows (in thousands):

	December 31, 2016
Face value	$ 10,000
Less: debt issuance costs	(119)
Total long-term loan	$ 9,881
Less: current portion of long-term loan	—
Total long-term loan, excluding current portion	$ 9,881

As of December 31, 2016, future principal payments due under the December 2016 Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2017	$ —
December 31, 2018	2,000
December 31, 2019	4,000
December 31, 2020	4,000
December 31, 2021	$ —
Total future principal payments due under the December 2016 Loan Agreement	$ 10,000

7. Stock-Based Compensation

Equity Incentive Plans

The Company adopted an Equity Incentive Plan, or the 2008 Plan, in 2008, under which no further shares of common stock are reserved for issuance to employees, nonemployee directors, and consultants of the Company. The Plan provides for the grant of incentive stock options, nonstatutory stock options, rights to purchase restricted stock, stock appreciation rights, dividend equivalents, stock payments, and restricted stock units to eligible recipients. 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 2,200,000 shares of common stock for issuance under the 2016 Plan, plus the 223,371 reserved and unissued shares under the 2008 plan on the effective date of the 2016 Plan. The number of shares reserved for issuance under the 2016 Plan will increase 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.

Recipients of incentive stock options shall be eligible to purchase shares of the Company’s common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Plan is ten years. The options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years. At December 31, 2016, 1,386,549 options remained available for future grant under the 2016 Plan.

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

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

Assumed volatility — Due to limited historical data, the expected volatility is estimated based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group consisted of other publicly-traded companies in the same industry and in a similar stage of development. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected life — Based based on the simplified method, which is an average of the contractual term of the options and its ordinary vesting period.

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

Common stock fair value — Upon the effective date of the IPO, the Company began using the closing price of its common stock for the price of new stock option awards. Prior to the effectiveness of the Company's IPO, given the absence of a public trading market, the Board of Directors considered numerous objective and subjective factors to determine the fair value of common stock at each grant date. These factors included, but were not limited to, (i) contemporaneous valuations of common stock performed by unrelated third-party specialists; (ii) the prices for preferred stock sold to outside investors; (iii) the rights, preferences and privileges of preferred stock relative to common stock; (iv) the lack of marketability of common stock; (v) developments in the business; and (vi) the likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of the Company, given prevailing market conditions.

The expense recognized for the portion of the award that is expected to vest has been reduced by an estimated forfeiture rate. The forfeiture rate is determined at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

	Year ended December 31,		
	2016	2015	2014
Assumed risk-free interest rate	1.40% -1.53%	1.57%	1.82% - 2.09%
Assumed volatility	52.91% - 53.49%	61.53%	71.09%
Expected option life	6.1 years	6.1 years	6.1 years
Expected dividend yield	—%	—%	—%

The Company recognized stock-based compensation straight-line over the vesting term of the options. The Company recorded 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,		
	2016	2015	2014
Cost of revenue	$ 46	$ 31	$ 30
Research and development	115	47	45
Selling, general and administrative	402	129	110
Total	$ 563	$ 207	$ 185

Unrecognized compensation expense at December 31, 2016 was approximately $5.1 million, which is expected to be recognized over a weighted-average term of 3.4 years.

Equity instruments issued to nonemployees are initially recorded at their grant-date fair value and are periodically revalued using the Black-Scholes option pricing model as the equity instruments vest and are recognized as expense over the related service period. Stock-based compensation expense to nonemployees was immaterial for the years ended December 31, 2016, 2015 and 2014.

The following table summarizes stock option transactions for the Plan for the years ended December 31, 2016, 2015 and 2014 (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, 2015	1,298,868	$ 1.44		
Options granted	1,787,517	5.88		
Options exercised	(808,885)	1.32		
Options canceled	(51,816)	3.41		
Outstanding at December 31, 2016	2,225,684	5.00	8.7	8,560
Vested and expected to vest at December 31, 2016	1,929,465	$ 4.81	8.6	7,792
Vested and exercisable at December 31, 2016	485,770	$ 1.92	5.8	3,368

The weighted-average fair value of options granted during the years ended December 31, 2016 was $2.99. The intrinsic value of options exercised for the years ended December 31, 2016 was $1.2 million and immaterial for the years ended December 31, 2015 and 2014.

All options outstanding under the 2008 Plan are exercisable under the early exercise provisions of the Plan. Options granted under the 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. For the year ended December 31, 2016, 252,453 options were early exercised and 238,638 remain unvested with a related liability of $0.2 million recorded under other current liabilities on the Company's consolidated balance sheet as of December 31, 2016. No options were early exercised for the years ended December 31, 2015 and 2014.

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 initially reserved 180,000 shares of common stock for issuance under the 2016 ESPP. The number of shares reserved for issuance under the 2016 ESPP will increase 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. Stock compensation expense related to the ESPP was immaterial for the year ended December 31, 2016 and is included in total stock compensation expense disclosed above.

8. Convertible Preferred Stock and Stockholders' Deficit

Convertible Preferred Stock

Convertible preferred stock prior to automatic conversion of all shares to common stock immediately prior to the closing of the IPO consisted of the following (in thousands, except for shares):

	Shares authorized	Shares issued and outstanding	Net carrying value	Aggregate liquidation preference
Series A	2,333,332	804,595	$ 6,773	$ 7,000
Series B	4,333,332	1,494,248	6,454	6,500
Series C	7,809,006	2,668,533	16,393	16,523
Series C-1	1,418,042	480,286	4,984	5,000
Series D	8,076,436	2,732,552	20,095	20,590
Series E	10,490,611	1,916,425	15,799	15,893
Total	34,460,759	10,096,639	$ 70,498	$ 71,506

Series E Preferred Stock

On May 4, 2016, the Company completed its Series E financing. The Company sold 1,916,425 shares of Series E stock at $8.2932 per share for proceeds of $15.8 million, net of $0.1 million in issuance costs, which includes a non-cash amount of $1.3 million issued to a

related party as further described in Note 11. The holders of Series E stock are entitled to receive dividends, if declared, at a rate of $0.6635 per annum. In the event of liquidation, the holders of Series E shares are entitled to receive liquidation preferences at the rate of $8.2932 per share. Each share of Series E stock is convertible to one share of common stock immediately upon (i) the Company's sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, in which per share price is at least $12.44 (as adjusted) or (ii) the affirmative vote of more than 67% of the holders of the then-outstanding preferred stock voting together as a single class.

As of December 31, 2015, the convertible preferred stock was classified as temporary equity in the accompanying balance sheet as the shares included provisions that allowed the holder to cause redemption of the shares upon certain changes in control events that are outside of the Company's control. An aggregate of 10,360,419 shares of common stock, excluding any warrant conversions, were issued to the holders of the Company's Series A, Series B, Series C, Series C-1, Series D and Series E convertible preferred stockholders upon the automatic conversion of all shares of convertible preferred stock to common stock immediately prior to the closing of the IPO. As a result, no Series A, Series B, Series C, Series C-1, Series D or Series E convertible preferred stock remain outstanding at December 31, 2016.

Outstanding Warrants

The following warrants were outstanding as of December 31, 2016:

	Shares	Weighted-average exercise price	Issuance date	Expiration date
Common stock warrants (1)	24,224	$ 6.1918	Feb 24, 2012	Feb 24, 2019

(1) Prior to conversion upon IPO, the remaining warrants were for the purchase of Series C preferred stock.

During the fourth quarter 2016, warrants for 61,112 shares of the Company's common stock were exercised via cashless exercise resulting in the issuance of 28,775 shares of common stock.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2016:

Stock options issued and outstanding	2,225,684
Authorized for future option grants	1,386,549
Warrants outstanding	24,224
Total	3,636,457

9. Income Taxes

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

	Year ended December 31,		
	2016	2015	2014
Current:			
Federal	$ —	$ —	$ —
State	2	2	2
Foreign		(15)	14
Total current provision	2	(13)	16
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred provision	—	—	—
Income tax provision (benefit)	$ 2	$ (13)	$ 16

The difference between income tax benefits and income taxes computed using the U.S. federal income tax rate as of December 31, 2016, 2015 and 2014 are as follows (in thousands):

	Year ended December 31,		
	2016	2015	2014
Federal provision (benefit)			
At statutory rates	$ (6,959)	$ (5,290)	$ (3,363)
State taxes, net of federal	—	1	1
Change in valuation allowance	6,961	5,291	3,364
Foreign operations	—	(15)	14
Income tax provision (benefit)	$ 2	$ (13)	$ 16

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. Until this analysis has been completed, the Company has removed deferred tax assets for Federal and California net operating losses of approximately $20.8 million and research and experimental credits of approximately $2.8 million generated through 2016 from its deferred tax schedule, and has recorded a corresponding decrease to its valuation allowance.

Significant components of the Company's deferred tax assets as are shown below:

	Year ended December 31,	
	2016	2015
Deferred tax assets:		
Foreign net operating losses	$ —	$ 388
Capitalized research and development	5,279	7,420
Other	259	111
Total gross deferred tax assets	5,538	7,919
Less valuation allowance	(5,538)	(7,919)
Total deferred tax assets	$ —	$ —

A valuation allowance of $5.5 million and $7.9 million as of December 31, 2016 and 2015, respectively, has been established to offset the deferred tax assets as realization of such assets are uncertain.

At December 31, 2016, the Company had federal and state net operating loss carryforwards of approximately $58.7 million and $14.4 million, respectively. Each of the federal and state tax loss carryforwards will begin expiring in 2028, unless previously utilized. The Company also has federal and California research and development tax credit carryforwards totaling $1.8 million and $1.6 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.

Commencing with the 2013 year, the Company computed its California net operating losses, or California NOLs, under the Multistate Tax Compact apportionment rules as provided for in the California Court of Appeal's decision in Gillette v. FTB. That decision was overturned by the California Supreme Court on December 31, 2015. As such, it is the Company's intent to compute its California apportionment factor, and resulting California NOLs, under California's Single Sales Factor Market rules. In 2015, the Company adjusted its California NOLs and deferred tax assets to the Single Sales Factor state rate. The impact to the California NOLs was approximately $(13.5) million.

The Company has not provided U.S. income taxes and foreign withholding taxes on the undistributed earnings of foreign subsidiaries as of December 31, 2015 and 2014, because it intends to permanently reinvest such earnings outside the United States. If these foreign earnings on these were to be repatriated in the future, the related U.S. tax liability may be reduced by any foreign income taxes previously paid on these earnings. Due to historical losses, as of December 31, 2015 and 2014, the foreign subsidiaries do not have cumulative earnings. As of December 31, 2016, all of these entities have been dissolved.

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, 2016, 2015 and 2014, the Company continued to have no unrecognized tax benefits. There are no unrecognized tax benefits included on the consolidated balance sheet sheets that would, if recognized, impact the effective tax rate. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

10. Commitments and Contingencies

The Company leases facilities under a noncancelable operating lease that expires on March 31, 2019. Under the terms of the facilities lease, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs.

We enter 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 and not included in the table below.

Future noncancelable minimum payment obligations under the operating lease were as follows as of December 31, 2016 (in thousands):

Year ended:		
December 31, 2017	$	248
December 31, 2018		397
December 31, 2019		100
Total future payments due under building lease	$	745

Rent expense totaled $0.3 million for the year ended December 31, 2016 and $0.2 million for the years ended December 31, 2015 and 2014.

11. Related Party Transactions

In June 2013, the Company and Bader Sultan & Bros. Co W.L.L., or Bader, a healthcare products distributor based in Sufat, Kuwait, entered into a distribution agreement, whereby the Company appointed Bader as a distributor of its products. Sales to Bader began in November 2013. The Company's agreement with Bader restricts Bader's ability to sell competing products and requires Bader to purchase a certain number of products from the Company monthly based on annual forecasts that the Company provides to Bader. If Bader does not resell the minimum purchase quantity specified in the contract by the applicable date, then the Company has the right, in its sole discretion, to sell to other distributors in the Middle East or terminate its agreement with Bader. The initial term of the agreement expires in December 2019. The agreement can be terminated by the Company immediately upon certain breaches by Bader, or by either Bader or the Company for uncured material breach of the agreement.

As part of the 2014 Series D convertible preferred stock financing, Bader purchased 875,903 shares of the Company's Series D convertible preferred stock. All terms of the purchase of preferred stock were the same for Bader as the other investors. Sales to Bader for the years ended December 31, 2016, 2015 and 2014 totaled $3.4 million, $3.8 million and $1.9 million, respectively, which represents 100%, 94.7% and 52.4% of total revenue for the respective years. As of December 31, 2016, the Company had accounts receivable from Bader of $0.5 million.

In January 2015, the Company and Bader amended the distribution agreement. In accordance with the amendment, Bader provided the Company with a deposit of $1.3 million, and committed to minimum product purchases for calendar year 2015. Under the terms of the amendment, the Company reserved the right to keep the deposit as liquidated damages if Bader did not meet the minimum product purchases. The Company classified the deposit as a current liability at December 31, 2015 on the consolidated balance sheets as the minimum product purchase levels were met. In April 2016, the Company and Bader entered into a Payment Direction Letter, resulting in the exchange of the distribution agreement deposit for 154,585 shares Series E convertible preferred stock at a price of $8.2932 per share. All of Bader's outstanding convertible preferred stock converted to common stock in connection with the Company's IPO.

12. Selected Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of the Company for the years ended December 31, 2016 and 2015 *(unaudited, in thousands, except for per share data)*:

2016:	Three Months Ended				Year Ended
	March 31,	June 30,	September 30,	December 31,	December 31,
Revenue	$ 1,069	$ 779	$ 773	$ 772	$ 3,393
Gross profit	447	107	129	(99)	584
Loss from operations	(3,444)	(4,075)	(4,452)	(7,534)	(19,505)
Net loss	$ (3,581)	$ (4,131)	$ (5,260)	$ (7,495)	$ (20,467)
Per common share:					
Net loss per share, basic and diluted	$ (6.22)	$ (7.15)	$ (5.46)	$ (0.51)	$ (4.85)

2015:	Three Months Ended				Year Ended
	March 31,	June 30,	September 30,	December 31,	December 31,
Revenue	$ 911	$ 1,052	$ 1,093	$ 983	$ 4,039
Gross profit	331	427	449	329	1,536
Loss from operations	(2,020)	(4,869)	(3,370)	(4,674)	(14,933)
Net loss	$ (2,133)	$ (5,024)	$ (3,562)	$ (4,838)	$ (15,557)
Per common share:					
Net loss per share, basic and diluted	$ (3.74)	$ (8.75)	$ (6.21)	$ (8.42)	$ (27.14)

13. Subsequent Events

Lease Extension

On February 15, 2017, the Company extended its facility lease agreement under a noncancelable operating lease that expires on March 31, 2019. All commitment tables previously presented reflect incorporation of the amendment.

Stock Option Grants

Subsequent to December 31, 2016, stock options for 0.1 million shares of the Company's common stock were granted to new Company employees, including the Company's new Board of Director member.

ITEM 16. Form 10-K Summary

None

SIGNATURES

Pursuant to the requirements 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 23, 2017 by: /s/ Andrew Rasdal
President and Chief Executive Officer

Date: February 23, 2017 by: /s/ William Plovanic
Chief Financial Officer

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Andrew Rasdal **Andrew Rasdal**	President and Chief Executive Officer and Director (Principal Executive Officer)	February 23, 2017
/s/ William Plovanic **William Plovanic**	Chief Financial Officer (Principal Financial Officer)	February 23, 2017
/s/ Nooshin Hussainy **Nooshin Hussainy**	Vice President of Finance (Principal Accounting Officer)	February 23, 2017
/s/ Kim Kamdar **Kim Kamdar**	Chairperson of the Board of Directors	February 23, 2017
/s/ Ray Dittamore **Ray Dittamore**	Director	February 23, 2017
/s/ Douglas Fisher **Douglas Fisher**	Director	February 23, 2017
/s/ Les Howe **Les Howe**	Director	February 23, 2017
/s/ Jonah Shacknai **Jonah Shacknai**	Director	February 23, 2017
/s/ Sharon Stevenson **Sharon Stevenson**	Director	February 23, 2017

INDEX TO EXHIBITS

Exhibit Number	Description of Document	Form	File No.	Exhibit Filing Date	Exhibit	Filed/Furnished Herewith
3.2	Restated Certificate of Incorporation	S-1	333-213551	9/26/16	3.2	
3.4	Restated Bylaws	S-1	333-213551	9/26/16	3.4	
4.1	Form of Common Stock Certificate	S-1	333-213551	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	333-213551	9/9/16	4.2	
4.3	Form of Warrant to Purchase Series C Preferred Stock	S-1	333-213551	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	333-213551	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	333-213551	9/9/16	4.5	
10.1‡	Form of Indemnity Agreement by and between the Registrant and its directors and officers	S-1	333-213551	9/26/16	10.1	
10.2‡	2008 Stock Plan and form of award agreements thereunder.	S-1	333-213551	9/9/16	10.2	
10.3‡	2016 Equity Incentive Plan and form of award agreements thereunder	S-1	333-213551	9/26/16	10.3	
10.4‡	2016 Employee Stock Purchase Plan and form of enrollment agreement	S-1	333-213551	9/26/16	10.4	
10.5‡	Obalon Therapeutics, Inc. Bonus Plan	S-1	333-213551	9/26/16	10.11	
10.6‡	Form of CEO Retention Agreement	10-Q	001-37897	11/10/16	10.6	
10.7‡	Form of Executive Retention Agreement (Non-CEO)	10-Q	001-37897	11/10/16	10.7	
10.8‡	Form of Non-Employee Director Option Agreement.					X
10.9‡	Offer Letter dated June 9, 2008 between the Registrant and Andrew Rasdal	S-1	333-213551	9/26/16	10.5	
10.10‡	Offer Letter dated June 16, 2008 between the Registrant and Mark Brister	S-1	333-213551	9/26/16	10.6	
10.11‡	Offer Letter dated November 24, 2008 between the Registrant and Amy VandenBerg	S-1	333-213551	9/26/16	10.7	
10.12	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	333-213551	9/9/16	10.8	
10.13	Amendment to Lease, dated January 30, 2017, by and between Pleta & San Gal Trusts dba: Ocean Point and Registrant.					X
10.14*	Distribution Agreement dated June 26, 2013 between the Registrant and Bader Sultan & Bros. Co. W.L.L., as amended	S-1	333-213551	9/9/16	10.9	
10.15	Loan and Security Agreement dated June 14, 2013 between the Registrant and Pacific Western Bank (as successor in interest to Square 1 Bank), as amended	S-1	333-213551	9/9/16		
10.16	Third Amendment to Loan and Security Agreement, dated December 21, 2016, between the Registrant and Pacific Western Bank					X

21.1	Subsidiaries of the Registrant.	S-1	333-213551	9/9/16	21.1	
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

* Registrant has omitted and filed separately with the SEC portions of the exhibit pursuant to confidential treatment request under Rule 406 promulgated under the Securities Act.

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

‡ Management contract or compensatory plan or arrangement.

Exhibit 10.8

NOTICE OF STOCK OPTION GRANT

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 Stock Option Grant (the "***Notice of Grant***") and the attached Stock Option Agreement, including any special terms and conditions for your country set forth in the appendix attached thereto (collectively, the "***Option Agreement***"). You have been granted an Option to purchase shares of Common Stock of the Company under the Plan subject to the terms and conditions of the Plan, this Notice of Grant and the Option Agreement.

Name: __

Date of Grant: __

Vesting Commencement Date: __

Exercise Price per Share: __

Total Number of Shares: __

Type of Option: _____ Non-Qualified Stock Option

_____ Incentive Stock Option

Expiration Date:_____; this Option expires earlier if your Service terminates earlier, as described in the Option Agreement.

Vesting Schedule; Acceleration:

This Option becomes exercisable with respect to the first 1/36th of the Shares subject to this Option when you complete one (1) month of Service from the Vesting Commencement Date. Thereafter, this Option becomes exercisable with respect to an additional 1/36th of the Shares subject to this Option when you complete each month of Service.

In the event of a Corporate Transaction (as defined in the Plan), this Option will become vested and exercisable in full as of immediately prior to the consummation of the Corporate Transaction.

You understand that your employment or consulting relationship with the Company or a Parent, Subsidiary or Affiliate is for an unspecified duration, can be terminated at any time, and that nothing in this Notice of Grant, the Option Agreement or the Plan changes the nature of that relationship. By accepting this Option, you and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan, this Notice of Grant and the Option Agreement. By accepting this Option, you consent to the electronic delivery and acceptance as further set forth in the Option Agreement.

OBALON THERAPEUTICS INC.

By: _____

Andrew Rasdal
President and CEO

STOCK OPTION AGREEMENT

OBALON THERAPEUTICS INC. 2016
EQUITY INCENTIVE PLAN

You have been granted an Option by Obalon Therapeutics Inc. (the "***Company***") under the 2016 Equity Incentive Plan (the "***Plan***") to purchase Shares (the "***Option***"), subject to the terms, restrictions and conditions of the Plan, the Notice of Stock Option Grant (the "***Notice of Grant***") and this Stock Option Agreement, including any special terms and conditions for your country set forth in the appendix attached hereto (the "***Appendix***") (collectively, the "***Agreement***").

1. Grant of Option. You have been granted the Option for the number of Shares set forth in the Notice of Grant at the Exercise Price per Share set forth in the Notice of Grant. In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of this Agreement, the terms and conditions of the Plan shall prevail.

If designated in the Notice of Grant as an Incentive Stock Option ("***ISO***"), this Option is intended to qualify as an Incentive Stock Option under Section 422 of the Code. However, if this Option is intended to be an ISO, to the extent that it exceeds the $100,000 limit under Code Section 422(d), it shall be treated as a Nonqualified Stock Option ("***NSO***").

2. Termination.

(a) General Rule. If your Service terminates for any reason except death or Disability, and other than for Cause, then this Option will expire at the close of business at Company headquarters on the date three months after your termination of Service (subject to the expiration detailed in Section 6). If your Service is terminated for Cause, this Option will expire upon the date of such termination.

You acknowledge and agree that the vesting schedule set forth in the Notice of Grant may change prospectively in the event that your service status changes between full and part-time status in accordance with Company policies relating to work schedules and vesting of awards. You acknowledge that the vesting of the Shares pursuant to this Agreement is earned only by continuing Service.

(b) Death; Disability. If you die before your Service terminates (or you die within three months of your termination of Service other than for Cause), then this Option will expire at the close of business at Company headquarters on the date 12 months after the date of death (subject to the expiration detailed in Section 6). If your Service terminates because of your Disability, then this Option will expire at the close of business at Company headquarters on the date 12 months after your termination date (subject to the expiration detailed in Section 6).

(c) Termination Date. For purposes of this Option, your Service will be considered terminated as of the date you are no longer actively providing services to the Company or a Parent, Subsidiary or Affiliate (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 engaged or the terms of your employment or consulting agreement, if any), and your period of Service will not include any contractual notice period or any period of "garden leave" or similar period mandated under labor laws in the jurisdiction where you are employed or engaged or the terms of your employment or consulting agreement, if any. The Committee shall have the exclusive discretion to determine when you are no longer actively providing services for purposes of this Option (including whether you may still be considered to be providing services while on a leave of absence).

(d) No Notice. You are responsible for keeping track of these exercise periods following your termination of Service for any reason. The Company will not provide further notice of such periods. In no event shall this Option be exercised later than the Expiration Date set forth in the Notice of Grant.

3. Exercise of Option.

(a) Right to Exercise. This Option is exercisable during its term in accordance with the vesting schedule set forth in the Notice of Grant and the applicable provisions of the Plan and this Agreement. In the event of your death, Disability, or other cessation of Service, the exercisability of the Option is governed by the applicable provisions of the Plan, the Notice of Grant and this Agreement. This Option may not be exercised for a fraction of a Share.

(b) Method of Exercise. This Option is exercisable by delivery of an exercise notice in a form specified by the Company (the "***Exercise Notice***"), which shall state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the "***Exercised Shares***"), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice shall be delivered in person, by mail, via electronic mail or facsimile or by other authorized method to the Secretary of the Company or other person designated by the Company. The Exercise Notice shall be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares. This Option shall be deemed to be exercised upon receipt by the Company of a fully executed Exercise Notice accompanied by the aggregate Exercise Price and any applicable withholding of Tax-Related Items as detailed in Section 8 below.

(c) Exercise by Another. If another person wants to exercise this Option after it has been transferred to him or her in compliance with this Agreement, that person must prove to the Company's satisfaction that he or she is entitled to exercise this Option. That person must also complete the proper Exercise Notice form (as described above) and pay the Exercise Price (as described below) and any applicable withholding of Tax-Related Items as described below.

4. Method of Payment. Payment of the aggregate Exercise Price shall be by any of the following, or a combination thereof, at your election:

(a) your personal check, wire transfer, or a cashier's check;

(b) for U.S. taxpayers only: certificates for shares of Company stock that you own, along with any forms needed to effect a transfer of those shares to the Company; the value of the shares, determined as of the effective date of the Option exercise, will be applied to the Exercise Price. Instead of surrendering shares of Company stock, you may attest to the ownership of those shares on a form provided by the Company and have the same number of shares subtracted from the Exercised Shares issued to you. However, you may not surrender, or attest to the ownership of, shares of Company stock in payment of the Exercise Price of your Option if your action would cause the Company to recognize compensation expense (or additional compensation expense) with respect to this Option for financial reporting purposes;

(c) cashless exercise through irrevocable directions to a securities broker approved by the Company to sell all or part of the Exercised Shares and to deliver to the Company from the sale proceeds an amount sufficient to pay the Exercise Price and any withholding of Tax-Related Items. The balance of the sale proceeds, if any, will be delivered to you. The directions must be given by signing a special notice of exercise form provided by the Company; or

(d) other method authorized by the Company.

5. Non-Transferability of Option. In general, except as provided below, only you may exercise this Option prior to your death. You may not transfer or assign this Option, except as provided below. For instance, you may not sell this Option or use it as security for a loan. If you attempt to do any of these things, this Option will immediately become invalid.

However, if you are a U.S. taxpayer, you may dispose of this Option in your will or in a beneficiary designation. If you are a U.S. taxpayer and this Option is designated as a NSO in the Notice of Grant, then

the Committee may, in its sole discretion, allow you to transfer this Option as a gift to one or more family members. For purposes of this Agreement, "family member" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in- law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law (including adoptive relationships), any individual sharing your household (other than a tenant or employee), a trust in which one or more of these individuals have more than 50% of the beneficial interest, a foundation in which you or one or more of these persons control the management of assets, and any entity in which you or one or more of these persons own more than 50% of the voting interest. In addition, if you are a U.S. taxpayer and this Option is designated as a NSO in the Notice of Grant, then the Committee may, in its sole discretion, allow you to transfer this Option to your spouse or former spouse pursuant to a domestic relations order in settlement of marital property rights. The Committee will allow you to transfer this Option only if both you and the transferee(s) execute the forms prescribed by the Committee, which include the consent of the transferee(s) to be bound by this Agreement.

This Option may not be transferred in any manner other than by will or by the laws of descent or distribution or court order and may be exercised during the lifetime of you only by you, your guardian, or legal representative, as permitted in the Plan and applicable local laws. The terms of the Plan and this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of you.

6. **Term of Option**. This Option shall in any event expire on the expiration date set forth in the Notice of Grant, which date is ten years after the grant date (five years after the grant date if this Option is designated as an ISO in the Notice of Grant and Section 5.3 of the Plan applies).

7. **Tax Consequences**. You should consult a tax adviser for tax consequences relating to this Option in the jurisdiction in which you are subject to tax. YOU SHOULD CONSULT A TAX ADVISER BEFORE EXERCISING THIS OPTION OR DISPOSING OF THE SHARES.

(a) Exercising the Option. You will not be allowed to exercise this Option unless you make arrangements acceptable to the Company to pay any withholding of Tax-Related Items.

(b) Notice of Disqualifying Disposition of ISO Shares. If you sell or otherwise dispose of any of the Shares acquired pursuant to an ISO on or before the later of (i) two years after the grant date, or (ii) one year after the exercise date, you shall immediately notify the Company in writing of such disposition. You agree that you may be subject to income tax withholding by the Company on the compensation income recognized from such early disposition of ISO Shares by payment in cash or out of the current compensation paid to you.

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 income tax, social insurance contributions, payroll tax, fringe benefits tax, payment on account or other tax-related withholding ("***Tax-Related Items***"), 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 this Option, including the grant, vesting or exercise of this Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends; and (2) do not commit to structure the terms of the grant or any aspect of this Option 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 exercise of the Option, you shall pay or make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Item 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. 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 you exercise this Option, 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 and pursuant to this authorization), (c) your payment of a cash amount, 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 of the Option exercise, 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.

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 your purchase of Shares 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.

9. **Nature of Grant.** In accepting this Option, 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, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

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

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

(d) you are voluntarily participating in the Plan;

(e) this Option and any Shares acquired under the Plan, and the income and value of same, are not intended to replace any pension rights or compensation;

(f) this Option and any Shares acquired under the Plan, and the income and value of same, are not part of normal or expected compensation for purpose of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement benefits or payments or welfare benefits or similar payments;

(g) unless otherwise agreed with the Company, this Option 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 any Parent, Subsidiary or Affiliate;

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

(i) if the underlying Shares do not increase in value, this Option will have no value;

(j) if you exercise this Option and acquire Shares, the value of such Shares may increase or decrease in value, even below the Exercise Price;

(k) no claim or entitlement to compensation or damages shall arise from forfeiture of this Option 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 employed or engaged or the terms of your employment or service agreement, if any), and in consideration of the grant of this Option to which you are otherwise not entitled, you irrevocably agree never to institute any claim against the Company, the Employer or any Parent, Subsidiary or Affiliate, waive your ability, if any, to bring any such claim, and release the Company, the Employer or any Parent, Subsidiary or Affiliate 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

(l) if you are providing Service outside the United States, neither the Employer, the Company nor any Parent, Subsidiary or Affiliate shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of this Option or of any amounts due to you pursuant to the exercise of this Option or the subsequent sale of any Shares acquired upon exercise.

10. 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 Agreement and any other Option grant materials by and among, as applicable, the Employer, the Company and any Parent, Subsidiary or Affiliate 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 or directorships held in the Company, details of all stock options or any other entitlement to shares 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 third parties in connection 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 recipient's 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, he or she 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 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 purposes 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 understands 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 Service status and career with the Employer will not be adversely affected; the only consequence of refusing or withdrawing your consent is that Company would not be able to grant you stock options 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.

11. **Acknowledgement**. The Company and you agree that this Option is granted under and governed by the Notice of Grant, this Agreement and the provisions of the Plan (incorporated herein by reference). 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 this Option subject to all of the terms and conditions set forth in this Agreement and those set forth in the Plan and the Notice of Grant. 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 of Grant and this Agreement.

12. **Consent to Electronic Delivery and Acceptance of All Plan Documents and Disclosures**. By your acceptance of this Option, you consent to the electronic delivery of the Notice of Grant, this Agreement, 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 this Option. 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 investor@obalon.com. 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 investor@obalon.com Finally, you understand that you are not required to consent to electronic delivery.

13. **Compliance with Laws and Regulations**. The exercise of this Option 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 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 Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

14. **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.

15. **Governing Law; Venue**. This Agreement and 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 of Grant and this 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.

16. **Severability**. If one or more provisions of this 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 Agreement, (ii) the balance of this Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of this Agreement shall be enforceable in accordance with its terms.

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

18. **Adjustment**. In the event of a stock split, a stock dividend or a similar change in Company stock, the number of Shares covered by this Option and the Exercise Price per Share may be adjusted pursuant to the Plan.

19. **Lock-Up Agreement**. In connection with the initial public offering of the Company's securities and upon request of the Company or the underwriters managing any underwritten offering of the Company's securities, you hereby agree not to sell, make any short sale of, loan, grant any Option for the purchase of, or otherwise dispose of any securities of the Company however and whenever acquired (other than those included in the registration) without the prior written consent of the Company or such underwriters, as the case may be, for such period of time (not to exceed one hundred eighty (180) days) from the effective date of such registration as may be requested by the Company or such managing underwriters and to execute an agreement reflecting the foregoing as may be requested by the underwriters at the time of the public offering; provided however that, if during the last seventeen (17) days of the restricted period the Company issues an earnings release or material news or a material event relating to the Company occurs, or prior to the expiration of the restricted period the Company announces that it will release earnings results during the sixteen (16)-day period beginning on the last day of the restricted period, then, upon the request of the managing underwriter, to the extent required by any FINRA rules, the restrictions imposed by this Section shall continue to apply until the end of the third trading day following the expiration of the fifteen (15)-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event. In no event will the restricted period extend beyond two hundred sixteen (216) days after the effective date of the registration statement.

20. **Award Subject to Company Clawback or Recoupment**. To the extent permitted by applicable law, the Option shall be subject to clawback or recoupment pursuant to any 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 you. In addition to any other remedies available under such policy, applicable law may require the cancellation of your Option (whether vested or unvested) and the recoupment of any gains realized with respect to your Option.

21. **Entire Agreement; Enforcement of Rights.** This Agreement, the Plan and the Notice of Grant 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 this Option are superseded. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, shall be effective unless in writing and signed by the parties to this Agreement. The failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of any rights of such party.

22. **Insider Trading Restrictions/Market Abuse Laws**. You acknowledge that 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.

23. **Language**. If you have received this 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.

24. **Appendix**. Notwithstanding any provisions in this Agreement, this Option 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 Agreement.

25. **Imposition of Other Requirements**. The Company reserves the right to impose other requirements on your participation in the Plan, on this Option 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.

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

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

APPENDIX TO
STOCK OPTION AGREEMENT

OBALON THERAPEUTICS INC. 2016
EQUITY INCENTIVE PLAN

Capitalized terms, unless explicitly defined in this Appendix, shall have the meanings given to them in the Stock Option Agreement, the Notice of Grant or in the Plan.

Terms and Conditions

This Appendix includes special terms and conditions that govern this Option if you reside and/or work in one of the countries listed below. If you are a citizen or resident (or are considered as such for local law purposes) of a country other than the country in which you are currently residing and/or working, or if you transfer to another country after receiving this Option, the Company shall, in its discretion, determine to what extent the special terms and conditions contained herein shall be applicable to you.

Notifications

This Appendix also includes information regarding securities, exchange control, tax and certain other issues of which you should be aware with respect to your participation in the Plan. The information is based on the securities, exchange control, tax and other laws in effect in the respective countries as of September 2016. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information contained herein as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time you exercise this Option or at the time you sell any Shares acquired under the Plan. In addition, the information is general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Therefore, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your individual situation.

If you are a citizen or resident (or are considered as such for local tax purposes) of a country other than the country in which you are currently residing and/or working, or if you transfer to another country after the grant of this Option, the information contained herein may not be applicable to you in the same manner.

UNITED STATES

There are no country-specific provisions.

Exhibit 10.13

AMENDMENT TO LEASE DATED JANUARY 30, 2017 BY AND BETWEEN PLETA & SAN GAL TRUSTS, DBA: OCEAN POINT, HEREINAFTER REFERRED TO AS "LESSOR" AND OBALON THERAPEUTICS INC., A DELAWARE CORPORATION, HEREINAFTER REFERRED TO AS "LESSEE".

The undersigned parties do hereby for the first time amend, affirm and ratify that certain Lease between the undersigned originally dated November 23, 2015, for premises located at 5421 Avenida Encinas, Suite J, Carlsbad, California 92008 and for the third time amend, affirm and ratify that certain Lease between the undersigned originally dated on or about October 3, 2011, as amended by the Amendment Renewal dated August 5, 2013, regarding the Lease of 5421 Avenida Encinas, Suites A through G, Carlsbad, California 92008 and generally described as the "Premises" (collectively the "Lease"). The terms used in this Amendment shall have the same definitions as those set forth in the Lease. This Amendment document shall be identified and referred to as the Third Amendment to the collective Lease.

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree that, subject to the full execution and delivery of this Amendment, the parties' respective rights and obligations under the Lease are hereby modified and amended as follows:

1. **PREMISES:** The Premises size shall be 17,500 total square feet by consolidating the Lease for Suites A-G and the Lease for Suite J in this amendment. Previous square footage for suites A-G contained 13,650 and previous Lease for suite J contained 3,850 square feet.

2. **TERM (Paragraph 1.3)**: The Expiration Date shall hereby be changed to March 31, 2019.

3. **RENTAL SCHEDULE (Paragraph 50)**: For this extended Term of the Lease, the following schedule for Base Rent and Common Area Operating Expenses (also referred to within the Lease as "CAM" or "CAM Charges") shall be in effect:

TERM	MONTHLY BASE RENT		MONTHLY ESTIMATED CAM		MONTHLY RENT
04/01/17 through 03/31/18	$29,750.00	+	$2,625.00	=	$32,375.00
04/01/18 through 03/31/19	$30,643.00	+	$2,625.00	=	$33,268.00

4. **RENTAL ABATEMENT**: Provided that Lessee is not in Default or Breach of this Lease, Base Rent shall be abated for months two (2) through four (4). In the event Lessee does not fulfill its obligations per the Lease, said Rental Abatement shall be recaptured per Paragraph 13.3 of the Lease.

5. **CAM CHARGES**: CAM Charges shall continue to be estimated for this extended Term of the Lease. CAM Charges as of the date of this Amendment are estimated to be $2,625.00 per month and shall be reconciled quarterly.

6. **RIGHT OF FIRST REFUSAL:** Lessee and Lessor agree that effective immediately, Lessee hereby forfeits the Right of First Refusal granted in the original Lease and will no longer hold the Right for the entire Project or any space within the Project.

7. **RESTORATION OF PREMISES:** Upon termination of the Lease, Lessee, at Lessees sole cost and expense, shall be obligated to remove Improvements as described on Exhibit A attached to this Amendment. In addition to the improvement restoration, Lessee is obligated at Lessee sole cost and expense, to ensure all electrical, HVAC and plumbing services are not comingled between meters. All excess communications and computer wires, cables and related devices in excess of one (1) set of the same, will be removed.

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8. **REPRESENTATION**: Sandra Watson of Gildred Development Company represents Lessor exclusively and Scot Ginsburg of Hughes Marino represents the Lessee in this transaction (please see Exhibit A to this Amendment, attached hereto and incorporated by this reference). Lessee and Lessor each represent and warrant to the other that no person, firm, broker or finder is entitled to any commission or finder's fee in connection herewith, except for Hughes Marino, which will receive a 3% commission paid on Base Rent collected for the extended term. Each of the Parties represents, acknowledges and agrees that it has been represented by such independent counsel and/or brokers, and has consulted with such consultants and other professionals, as each such Party has deemed necessary or appropriate and as it has voluntarily chosen throughout all negotiations which preceded the execution of this Amendment; and that this Amendment has been executed on the advice of such independent counsel, broker(s), consultant(s) and other professional(s). The Parties further agree that each has cooperated and participated in the drafting of this Amendment and, therefore, any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not apply in the interpretation of this Amendment.

9. **CONFIDENTIALITY**: Lessee agrees that the terms of this Lease will be kept strictly confidential and not disclosed to any other person without written consent from Lessor. Disclosure to persons or tenants other than the Lessee will constitute a material uncurable Breach of this Lease.

10. **GENERAL PROVISIONS:**

A. Lessee and Lessor further covenants and agrees that: (i) Lessor/Lessee has fully performed or satisfied all obligations of Lessor/Lessee under or in connection with, and Lessor/Lessee is not in breach of any term or condition of the Lease; (ii) any and all required work or contributions of Lessor to or on account of any tenant improvements respecting the Premises have been fully satisfied or received; and (iii) there are no defenses, offsets, counterclaims, or deductions against rents or other sums due to Lessor respecting the Premises, or which Lessee has against Lessor's enforcement of the Lease.
B. Except as otherwise provided herein, the provisions of this Amendment shall be deemed to obligate, extend to, and inure to the benefit of the successors, assigns, agents, principals, transferees, grantees, trustors, representatives, beneficiaries, insurers and indemnitees of each of the parties.
C. In the event that any provision of this Amendment is in conflict with any provision of the Lease, the conflicting provision of this Amendment shall take precedence and govern. Except as otherwise specified herein, the Lease remains in full force and effect.
D. If either Party hereto is a corporation, trust, limited liability company, partnership, or similar entity, each individual executing this Amendment on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Amendment on its behalf.
E. The Article, Section and other headings of this Amendment are for convenience of reference only and shall not be construed to affect the meaning of any provision contained herein.

LESSOR **LESSEE**
PLETA & SAN GAL TRUSTS, **OBALON THERAPEUTICS, INC.,**
DBA: OCEAN POINT **A DELAWARE CORPORATION**

By: /s/ Gregg Haggart By: /s/ Andrew Rasdal
Gregg Haggart, Special Trustee Andrew Rasdal, Chief Executive Officer

Date: 2/15/2017 Date: 2/9/2017

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EXHIBIT B
DISCLOSURE REGARDING
REAL ESTATE AGENCY RELATIONSHIP

(As required by the Civil Code)

When you enter into a discussion with a real estate agent regarding a real estate transaction, you should from the outset understand what type of agency relationship or representation you wish to have with the agent in the transaction.

SELLER'S AGENT ("Seller" includes both a vendor and a lessor)

A Seller's agent under a listing agreement with the Seller acts as the agent for the Seller only. A Seller's agent or a subagent of that agent has the following affirmative obligations:

To the Seller: A Fiduciary duty of utmost care , integrity, honesty and loyalty in dealings with the Seller. To the Buyer and the Seller: (a) Diligent exercise of reasonable skill and care in performance of the agent's duties.

(b) A duty of honest and fair dealing and good faith.

(c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the parties. An agent is not obligated to reveal to either party any confidential information obtained from the other party that does not involve the affirmative duties set forth above.

BUYER'S AGENT ("Buyer" includes both a purchaser and a lessee).

A selling agent can, with a Buyer's consent, agree to act as agent for the Buyer only. In these situations, the agent is not the Seller's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the Seller. An agent acting only for a Buyer has the following affirmative obligations:

To the Buyer: A fiduciary duty of utmost care , integrity, honesty and loyalty in dealings with the Buyer. To the Buyer and the Seller: (a) Diligent exercise of reasonable skill and care in performance of the agent's duties.

(b) A duty of honest and fair dealing and good faith.

(c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the parties.

An agent is not obligated to reveal to either party any confidential information obtained from the other party that does not involve the affirmative
Duties set forth above.

AGENT REPRESENTING BOTH SELLER AND BUYER

A real estate agent, either acting directly or through one or more associate licensees, can legally be the agent of both the Seller and the Buyer in a transaction, but only with the knowledge and consent of both the Seller and the Buyer.

In a dual agency situation, the agent has the following affirmative obligations to both the Seller and the Buyer:

(a) A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either the Seller or the Buyer.

(b) Other duties to the Seller and the Buyer as stated above in their respective sections.

In representing both Seller and Buyer, the agent may not, without the express permission of the respective party, disclose to the other party that the Seller will accept a price less than the listing price or that the Buyer will pay a price greater than the price offered. The above duties of the agent in a real estate transaction do not relieve a Seller or Buyer from the responsibility to protect his or her own interests. You should carefully read all agreements to assure that they adequately express your understanding of the transaction. A real estate agent is a person qualified to advice about real estate. If legal or tax advice is desired, consult a competent professional.

Throughout your real property transaction, you may receive more than one disclosure form, depending upon the number of agents assisting in the transaction. The law requires each agent with whom you have more than a casual relationship to present you with this disclosure form. You should read its contents each time it is presented to you, considering the relationship between you and the real estate agent in your specific transaction.

This disclosure form includes the provisions of Sections 2079.13 to 2079.24, inclusive, of the Civil Code set forth on page 2. Read it carefully. I/WE ACKNOWLEDGE RECEIPT OF A COPY OF THIS DISCLOSURE AND THE PORTIONS OF THE CIVIL CODE PRINTED ON THE BACK (OR A SEPARATE PAGE).

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LESSEE REPRESENTED BY HUGHES MARINO – SCOT GINSBERG ACKNOWLEDGED BY LESSEE:

By: /s/ Andrew Rasdal Date: 2/9/2017
Andrew Rasdal, Chief Executive Officer

SANDRA WATSON OF GILDRED DEVELOPMENT REPRESENTS LESSOR EXCLUSIVELY:

ACKNOWLEDGED BY LESSOR:

By: /s/ Gregg Haggart Date: 2/15/2017
Gregg Haggart, Special Trustee

Agent: Gildred Development Company /Gregg Haggart BRE Lic. # 01071252 / 00941329
Real Estate Broker (Firm)
By: Sandra Watson BRE Lic. # 01031752 Date: 11/30/2015
(Salesperson or Broker-Associate)

DISCLOSURE REGARDING REAL ESTATE AGENCY RELATIONSHIP

CIVIL CODE SECTIONS 2079.13 THROUGH 2079.24 (2079.16 APPEARS ON THE FRONT)

2079.13 As used in Sections 2079.14 to 2079.24, inclusive, the following terms have the following meanings:
(a) "Agent" means a person acting under provisions of Title 9 (commencing with Section 2295) in a real property transaction, and includes a person who is licensed as a real estate broker under Chapter 3 (commencing with Section 10130) of Part 1 of Division 4 of the Business and Professions Code, and under whose license a listing is executed or an offer to purchase is obtained. **(b) "**Associate licensee" means a person who is licensed as a real estate broker or salesperson under Chapter 3 (commencing with Section 10130) of Part 1 of Division 4 of the Business and Professions Code and who is either licensed under a broker or has entered into a written contract with a broker to act as the broker's agent in connection with acts requiring a real estate license and to function under the broker's supervision in the capacity of an associate licensee. The agent in the real property transaction bears responsibility for his or her associate licensees who perform as agents of the agent. When an associate licensee owes a duty to any principal, or to any buyer or seller who is not a principal, in a real property transaction, that duty is equivalent to the duty owed to that party by the broker for whom the associate licensee functions. **(c)** "Buyer" means a transferee in a real property transaction, and includes a person who executes an offer to purchase real property from a seller through an agent, or who seeks the services of an agent in more than a casual, transitory, or preliminary manner, with the object of entering into a real property transaction. "Buyer" includes vendee or lessee. **(d)** "Commercial real property" means all real property in the state, except single-family residential real property, dwelling units made subject to Chapter 2 (commencing with Section 1940) of Title 5, mobile homes, as defined in Section 798.3, or recreational vehicles, as defined in Section 799.29. **(e) "**Dual agent" means an agent acting, either directly or through an associate licensee, as agent for both the seller and the buyer in a real property transaction. **(f) "**Listing agreement" means a contract between an owner of real property and an agent, by which the agent has been authorized to sell the real property or to find or obtain a buyer. **(g) "**Listing agent" means a person who has obtained a listing of real property to act as an agent for compensation. **(h) "**Listing price" is the amount expressed in dollars specified in the listing for which the seller is willing to sell the real property through the listing agent. **(i)** "Offering price" is the amount expressed in dollars specified in an offer to purchase for which the buyer is willing to buy the real property. **(j)** "Offer to purchase" means a written contract executed by a buyer acting through a selling agent that becomes the contract for the sale of the real property upon acceptance by the seller. **(k) "**Real property" means any estate specified by subdivision (1) or (2) of Section 761 in property that constitutes or is improved with one to four dwelling units, any commercial real property, any leasehold in these types of property exceeding one year's duration, and mobile homes, when offered for sale or sold through an agent pursuant to the authority contained in Section 10131.6 of the Business and Professions Code. **(l)** "Real property transaction" means a transaction for the sale of real

property in which an agent is employed by one or more of the principals to act in that transaction, and includes a listing or an offer to purchase.
(m) "Sell," "sale," or "sold" refers to a transaction for the transfer of real property from the seller to the buyer, and includes exchanges of real property between the seller and buyer, transactions for the creation of a real property sales contract within the meaning of Section 2985, and transactions for the creation of a lease hold exceeding one year's duration. **(n)** "Seller" means the transferor in a real property transaction, and includes an owner who lists real property with an agent, whether or not a transfer results, or who receives an offer to purchase real property of which he or she is the owner from an agent on behalf of another. "Seller" includes both a vendor and a lessor. **(o)** "Selling agent" means a listing agent who acts alone, or an agent who acts in cooperation with a listing agent, and who sells or finds and obtains a buyer for the real property, or an agent who locates property for a buyer or who finds a buyer for a property for which no listing exists and presents an offer to purchase to the seller. **(p)** "Subagent" means a person to whom an agent delegates agency powers as provided in Article 5 (commencing with Section 2349) of Chapter 1 of Title 9. However, "subagent" does not include an associate licensee who is acting under the supervision of an agent in a real property transaction.

2079.14 Listing agents and selling agents shall provide the seller and buyer in a real property transaction with a copy of the disclosure form specified in Section 2079.16, and, except as provided in subdivision (c), shall obtain a signed acknowledgement of receipt from that seller or buyer, except as provided in this section or Section 2079.15, as follows: **(a)** The listing agent, if any, shall provide the disclosure form to the seller prior to entering into the listing agreement. **(b)** The selling agent shall provide the disclosure form to the seller as soon as practicable prior to presenting the seller with an offer to purchase, unless the selling agent previously provided the seller with a copy of the disclosure form pursuant to subdivision (a).
(c) Where the selling agent does not deal on a face-to-face basis with the seller, the disclosure form prepared by the selling agent may be furnished to the seller (and acknowledgement of receipt obtained for the selling agent from the seller) by the listing agent, or the selling agent may deliver the disclosure form by certified mail addressed to the seller at his or her last known address, in which case no signed acknowledgement of receipt is required. **(d)** The selling agent shall provide the disclosure form to the buyer as soon as practicable prior to execution of the buyer's offer to purchase, except that if the offer to purchase is not prepared by the selling agent, the selling agent shall present the disclosure form to the buyer not later than the next business day after the selling agent receives the offer to purchase from the buyer.

2079.15 In any circumstance in which the seller or buyer refuses to sign an acknowledgement of receipt pursuant to Section 2079.14, the agent, or an associate licensee acting for an agent, shall set forth, sign, and date a written declaration of the facts of the refusal.

2079.16 Reproduced on Page 1 of this form.
2079.17 (a) As soon as practicable, the selling agent shall disclose to the buyer and seller whether the selling agent is acting in the real property transaction exclusively as the buyer's agent, exclusively as the seller's agent, or as a dual agent representing both the buyer and the seller. This relationship shall be confirmed in the contract to purchase and sell real property or in a separate writing executed or acknowledged by the seller, the buyer, and the selling agent prior to or coincident with execution of that contract by the buyer and the seller, respectively. **(b)** As soon as practicable, the listing agent shall disclose to the seller whether the listing agent is acting in the real property transaction exclusively as the seller's agent, or as a dual agent representing both the buyer and seller. This relationship shall be confirmed in the contract to purchase and sell real property or in a separate writing executed or acknowledged by the seller and the listing agent prior to or coincident with the execution of that contract by the seller.
(c) The confirmation required by subdivisions (a) and (b) shall be in the following form.

(d) The disclosures and confirmation required by this section shall be in addition to the disclosure required by Section 2079.14.
2079.18 No selling agent in a real property transaction may act as an agent for the buyer only, when the selling agent is also acting as the listing agent in the transaction.
2079.19 The payment of compensation or the obligation to pay compensation to an agent by the seller or buyer is not necessarily determinative of a particular agency relationship between an agent and the seller or buyer. A listing agent and a selling agent may agree to share any compensation or commission paid, or any right to any compensation or commission for which an obligation arises as the result of a real estate transaction, and the terms of any such agreement shall not necessarily be determinative of a particular relationship.
2079.20 Nothing in this article prevents an agent from selecting, as a condition of the agent's employment, a specific form of agency relationship not specifically prohibited by this article if the requirements of Section 2079.14 and Section 2079.17 are complied with.
2079.21 A dual agent shall not disclose to the buyer that the seller is willing to sell the property at a price less than the listing price, without the express written consent of the seller. A dual agent shall not disclose to the seller that the buyer is willing to pay a price greater than the offering price, without the express written consent of the buyer. This section does not alter in any way the duty or responsibility of a dual agent to any principal with respect to confidential information other than price.
2079.22 Nothing in this article precludes a listing agent from also being a selling agent, and the combination of these functions in one agent does not, of itself, make that agent a dual agent.

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2079.23 A contract between the principal and agent may be modified or altered to change the agency relationship at any time before the performance of the act which is the object of the agency with the written consent of the parties to the agency relationship.
2079.24 Nothing in this article shall be construed to either diminish the duty of disclosure owed buyers and sellers by agents and their associate licensees, subagents, and employees or to relieve agents and their associate licensees, subagents, and employees from liability for their conduct in connection with acts governed by this article or for any breach of a fiduciary duty or a duty of disclosure.

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Exhibit 10.16

THIRD AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This Third Amendment to Loan and Security Agreement (the "***Amendment***"), is made and entered into as of December 21, 2016, by and among PACIFIC WESTERN BANK, a California state chartered bank ("***Bank***") and OBALON THERAPEUTICS, INC. and OBALON THERAPEUTICS, LLC (each a "***Borrower***", and collectively, "***Borrowers***").

RECITALS

Borrowers and Bank are parties to that certain Loan and Security Agreement dated as of June 14, 2013 (as amended from time to time, with related documents, the "***Agreement***"). The parties desire to amend the Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1) Bank and Borrowers hereby agree that that certain Third Warrant to Purchase Stock issued by Obalon Therapeutics, Inc. to Bank on September 7, 2016 is hereby cancelled without exercise.

2) Section 2.1(b) of the Agreement is hereby amended and restated, as follows:

(b) Term Loans.

(i) Term Loan A. Subject to and upon the terms and conditions of this Agreement, on December 21, 2016 or as soon thereafter as all conditions precedent to the making thereof have been met, Bank shall make a term loan to Borrowers in the principal amount of $10,000,000 (the "Term Loan A"). The proceeds of the Term Loan A shall be used to refinance the aggregate principal amount of all indebtedness owing from Borrowers to Bank as of December 21, 2016.

(ii) Term Loans B. Subject to and upon the terms and conditions of this Agreement, Bank agrees to make one (1) or more term loans to Borrowers in an aggregate principal amount not to exceed $5,000,000 (each a "Term Loan B" and collectively the "Term Loans B", and together with the Term Loan A, each a "Term Loan" and collectively, the "Term Loans"). Borrowers may request Term Loans B at any time on or before the Availability End Date. The proceeds of the Term Loans B shall be used for general working capital purposes and for capital expenditures.

(iii) Interest shall accrue from the date of each Term Loan at the rate specified in Section 2.3(a), and prior to the Interest-Only End Date shall be payable monthly beginning on the first day of the month next following such Term Loan, and continuing on the same day of each month thereafter. Any Term Loans outstanding on the Interest-Only End Date shall be payable in equal monthly installments of principal, plus all accrued interest, beginning on the date that is one month immediately following the Interest-Only End Date, and continuing

on the same day of each month thereafter through the Term Loan Maturity Date, at which time all amounts due in connection with the Term Loans and any other amounts due under this Agreement shall be immediately due and payable. Term Loans, once repaid, may not be reborrowed. Borrowers may prepay any Term Loan without penalty or premium.

(iv) When Borrowers desire to obtain a Term Loan B, Borrowers shall notify Bank (which notice shall be irrevocable) by facsimile transmission to be received no later than 3:30 p.m. Eastern time on the day on which the Term Loan B is to be made. Such notice shall be substantially in the form of Exhibit C. The notice shall be signed by an Authorized Officer.

3) Section 2.1(c) of the Agreement is hereby deleted.

4) Section 6.6 of the Agreement is hereby amended and restated, as follows:

6.6 Accounts. Borrowers shall at all times maintain Cash in accounts at Bank in an aggregate amount equal to or greater than the aggregate amount of all Indebtedness of Borrowers to Bank then outstanding.

5) Section 6.7 of the Agreement is hereby amended and restated, as follows:

6.7 [Reserved].

6) The following defined terms in Exhibit A to the Agreement are hereby amended and restated, as follows:

"Availability End Date" means December 21, 2017.

"Interest-Only End Date" means June 21, 2018.

"Term Loan Maturity Date" means December 21, 2020.

7) Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Agreement. The Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Bank under the Agreement, as in effect prior to the date hereof. Each Borrower ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement.

8) Each Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct as of the date of this Amendment.

9) This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

10) As a condition to the effectiveness of this Amendment, Bank shall have received, in form and substance satisfactory to Bank, the following:

(a) this Amendment, duly executed by each Borrower;

(b) payment of a $15,000 facility fee, which may be debited from any Borrower's accounts;

(c) payment of all Bank Expenses, including Bank's expenses for the documentation of this amendment and any related documents, and any UCC, good standing or intellectual property search or filing fees, which may be debited from any Borrower's accounts; and

(d) such other documents and completion of such other matters, as Bank may reasonably deem necessary or appropriate.

[Signature Page Follows]

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

OBALON THERAPEUTICS, INC.

By: /s/ Andrew Rasdal
Name: Andrew Rasdal
Title: Chief Executive Officer

OBALON THERAPEUTICS, LLC

By: /s/ Andrew Rasdal
Name: Andrew Rasdal
Title: Chief Executive Officer

PACIFIC WESTERN BANK

By: /s/ Sean Noonan
Name: Sean Noonan
Title: Vice President

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 statement (No. 333-213988) on Form S-8 of Obalon Therapeutics, Inc. of our report dated February 23, 2017, with respect to the consolidated balance sheets of Obalon Therapeutics, Inc. and subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2016, which report appears in the December 31, 2016 annual report on Form 10-K of Obalon Therapeutics, Inc.

/s/ KPMG LLP

San Diego, California
February 23, 2017

Exhibit 31.1

CERTIFICATION

I, Andrew Rasdal, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the 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

(c) 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 person 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 23, 2017

/s/ Andrew Rasdal

Andrew Rasdal
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

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)) 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) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the 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

(c) 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 person 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 23, 2017

/s/ William Plovanic

William Plovanic
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, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Andrew Rasdal, the President and Chief Executive Officer, and William Plovanic, 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 knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) 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 23, 2017

/s/ Andrew Rasdal	/s/ William Plovanic
Andrew Rasdal	William Plovanic
President and Chief Executive Officer (Principal Executive Officer)	Chief Financial Officer (Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.