5,000,000 Shares

OBALON

Obalon Therapeutics, Inc.

Common Stock

This is the initial public offering of our common stock. No public market currently exists for our common stock. We are offering all of the 5,000,000 shares of common stock offered by this prospectus. We expect the initial public offering price to be between $14.00 and $16.00 per share.

We have applied to list our common stock on The NASDAQ Global Market under the symbol "OBLN."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common stock in "Risk factors" beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) We refer you to "Underwriting" for additional information regarding total underwriting compensation.

Certain of our stockholders and their affiliates, some of which are affiliated with our directors, have indicated an interest in purchasing shares of common stock in this offering with an aggregate value of approximately $20.0 million at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these parties as they will on any other shares sold to the public in this offering.

The underwriters may also purchase up to an additional 750,000 shares of our common stock at the public offering price, less the underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus.

The underwriters expect to deliver the shares of common stock to investors on or about , 2016.

UBS Investment Bank **Canaccord Genuity** **Stifel**

BTIG

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Prospectus summary

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections "Risk factors" and "Management's discussion and analysis of financial condition and results of operations." Unless the context otherwise requires, we use the terms "Obalon," "company," "we," "us" and "our" in this prospectus to refer to Obalon Therapeutics, Inc. and our consolidated subsidiary.

OUR BUSINESS

We are a commercial-stage 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 swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients. We recently received premarket approval, or PMA, from the U.S. Food and Drug Administration, or 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. 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. We anticipate commencing the U.S. commercial launch of our Obalon balloon system in early 2017.

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.

Having received PMA approval for the Obalon balloon system, we are currently focused on commencing U.S. commercialization using a direct sales force, which we anticipate will occur in early 2017. We initially plan to sell the Obalon balloon system on a self-pay basis to bariatric surgeons and gastroenterologists with existing weight loss practices. We believe the design features of the Obalon balloon system will enable us to penetrate these existing physician specialties and later expand into new specialties, such as plastic surgery.

In 2012, we began selling an earlier generation of our Obalon balloon system in a limited number of countries outside of the United States through a combination of direct sales efforts and distributors. In 2015, we refocused our efforts toward developing and seeking regulatory approval for our balloon system in the United States and discontinued most of our international sales efforts other than our sales to Bader Sultan & Bros. Co. W.L.L., our distributor in the Middle East and one of our significant stockholders. As of June 30, 2016, we had sold over 23,000 of our earlier generation Obalon balloon systems for commercial use outside the United States.

THE OBESITY EPIDEMIC

Obesity is one of the largest, most debilitating, costly and underserved disease states globally. In adults, the disease is linked to several co-morbidities, including hypertension, type 2 diabetes, high blood pressure, certain cancers and other chronic conditions, 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.

Current treatment alternatives for obese patients begin with lifestyle modification, such as diet and exercise. If this alternative fails to produce the desired results, physicians may prescribe pharmaceutical therapies, typically to obese or overweight patients with a lower BMI. Although pharmaceutical therapies have been effective in assisting with weight loss, they are often associated with safety risks and negative side effects that may limit patient compliance. In obese patients with a higher BMI, physicians may pursue aggressive surgical treatments, such as gastric bypass and gastric banding. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size; however, they present substantial side effects and carry short- and long-term safety risks that have limited adoption. Importantly, bariatric surgical procedures can result in permanent changes to the patient's anatomy, are often associated with significant reoperation rates, typically involve extended hospitalization and can result in patient intolerance to common foods.

Recently, new medical procedures have been introduced in an attempt to address the gap in care between pharmaceutical treatment and invasive surgical procedures. These new procedures have included neuroblocking therapy, aspiration therapy and traditional intragastric balloons. The traditional intragastric balloons currently available in the U.S. market were approved for use in 2015. These balloons are large, saline-filled silicone devices that must be both placed in the stomach and later removed with an endoscopic procedure performed under anesthesia. While in the stomach, the balloons fill space, creating a sense of fullness in the patient. Traditional intragastric balloons have been associated with successful weight loss. However, we believe traditional intragastric balloons suffer limitations that are impeding their adoption, including their rate of SADEs, a lack of comfort and tolerability, a limited ability to provide progressive and sustained weight loss and an inconvenient placement procedure.

OUR SOLUTION

We designed the Obalon balloon system to address many of the limitations of traditional intragastric balloons. We believe the Obalon balloon system offers patients and physicians the following benefits:

- **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 June 2016, we had sold over 23,000 units of our earlier generation Obalon balloon systems in international markets and had only nine 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.** Our Obalon balloon is filled with a proprietary mix of gas, as opposed to heavier saline solutions used in traditional intragastric balloons. Our system is designed to use three Obalon balloons over the course of treatment, allowing the volume in the stomach to be gradually increased. 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 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 entire six-month balloon treatment period, and maintained, on average, 89.5% of the weight loss 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 Obalon balloon. A microcatheter is attached to the balloon to enable inflation and is subsequently detached and removed from the patient. Placement typically occurs in less than ten minutes and patients can return to normal activity once the placement is complete. 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. 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 and gastroenterology.** We plan to initially focus on direct sales to the leading bariatric surgeons and gastroenterologists in the United States. 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 plan to 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.
- **Expand into new physician channels.** We also plan to target additional physician specialties that have access to obese patients, including the 1,900 aesthetically focused plastic surgeons. We believe that plastic surgeons are among the physicians that have access to patients appropriate for the Obalon balloon system, have experience managing self-pay centers and have the capability to learn and perform Obalon balloon placements.
- **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. Our development pipeline includes an automated, easier-to-use inflation system, 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 that allows us to control the manufacturing and assembly of our products 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 intend to aggressively protect and enforce our intellectual property, both for existing and new products.

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.

Swallowable Capsule **EzFill Inflation System** **Gas-Filled Balloon**

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.

PRODUCT PIPELINE

We are leveraging our proprietary product technology and research and development expertise to develop additional products and product enhancements that improve clinical outcomes, increase ease of

use and reduce cost. These include a vegetable-derived balloon capsule, our EzPz inflation system, which is being designed to be automated and simpler to operate, a navigation system that could reduce the need for digital imaging at each balloon placement, a longer-term balloon that could be used to provide treatment for up to one year and a deflateable-passable balloon that could potentially eliminate the need for an endoscopic procedure to remove the balloons.

RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk factors" immediately following this prospectus summary. Some of these risks are:

- we have limited operating experience and a history of net losses, and we may not be able to achieve or sustain profitability;
- 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;
- 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;
- we may be unable to convince physicians to adopt our Obalon balloon system and recommend it to their patients;
- the effectiveness and safety of our Obalon balloon system depends critically on our ability to educate physicians on its safe and proper use;
- patients may experience SADEs as the result of the misuse or malfunction of, or design flaws in, our products;
- our success depends on our ability to obtain FDA approval or other regulatory approvals for our future products and product improvements; and
- we may be unable to adequately protect our proprietary technology and maintain issued patents that are sufficient to protect our Obalon balloon system.

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.

We have registered the trademarks "Obalon" in the United States and several foreign countries, "Obalon Swallowable Balloon" in the European Union and our Obalon logo in Mexico. We have trademark applications pending for "EzPz" in the United States and several foreign countries and for "OGB" and "EzFill" in the United States. Additionally, our Obalon logo and all product names are our common law trademarks. All other service marks, trademarks and trade names appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

IMPLICATIONS OF BEING AN EMERGING GROWTH COMPANY

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's discussion and analysis of financial condition and results of operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of the fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues equal or exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

The offering

Common stock offered by us	5,000,000 shares (or 5,750,000 shares if the underwriters exercise their option to purchase additional shares in full).
Common stock to be outstanding after this offering	15,953,471 shares (or 16,703,471 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $67.4 million, or approximately $77.8 million if the underwriters exercise their option to purchase additional shares in full, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for the commercialization of our Obalon balloon system, continued research and development efforts and working capital and other general corporate purposes. See "Use of proceeds."
Potential insider participation	Certain of our stockholders and their affiliates, some of which are affiliated with our directors, have indicated an interest in purchasing shares of common stock in this offering with an aggregate value of approximately $20.0 million at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these parties as they will on any other shares sold to the public in this offering.
Directed share program	At our request, the underwriters have reserved up to 5% of the common stock being offered by this prospectus for sale at the initial public offering price to our directors, officers, employees and other individuals associated with us and members of their families. The sales will be made by UBS Financial Services Inc., a selected dealer affiliated

	with UBS Securities LLC, an underwriter of this offering, through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock. Participants in the directed share program who purchase $1,000,000 or more of shares of our common stock will be subject to a 25-day lock-up with respect to any shares sold to them pursuant to the program. Any shares sold in the directed share program to our directors or executive officers will be subject to a 180-day lock-up. All of these lock-up agreements will have similar restrictions to the lock-up agreements described herein. See "Underwriting—Directed share program."
Risk factors	See "Risk factors" for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed NASDAQ Global Market symbol.....	"OBLN"

The number of shares of our common stock to be outstanding after this offering is based on 10,953,471 shares of our common stock outstanding as of June 30, 2016, which assumes the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2016 into an aggregate of 10,360,419 shares of common stock immediately prior to the closing of this offering, and 12,217 shares that we expect to issue upon the automatic net exercise of warrants immediately prior to the closing of this offering, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and excludes:

- 1,767,690 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2016, with a weighted-average exercise price of $1.41 per share;
- 229,528 shares of common stock issuable upon the exercise of stock options granted after June 30, 2016, with an exercise price of $2.82 per share;
- 60,786 shares of common stock issuable upon the exercise of warrants to purchase shares of preferred stock outstanding as of June 30, 2016, with a weighted-average exercise price of $7.40 per share, which will become warrants to purchase 60,786 shares of common stock upon the closing of this offering; and
- 3,436,415 shares of common stock reserved for future issuance under our stock-based compensation plans as of June 30, 2016, consisting of (i) 1,056,415 shares of common stock reserved for future issuance under our 2008 Equity Incentive Plan as of June 30, 2016, which was reduced to 447,719 shares on July 17, 2016, (ii) 2,200,000 shares of common stock reserved for future issuance under our 2016 Equity Incentive Plan, which will become effective on the date immediately prior to

the effective date of the registration statement of which this prospectus is a part, and (iii) 180,000 shares of common stock reserved for future issuance under our 2016 Employee Stock Purchase Plan, which will become effective on the effective date of the registration statement of which this prospectus is a part. Upon the effective date of the 2016 Equity Incentive Plan, any remaining shares available for issuance under our 2008 Equity Incentive Plan will be added to the shares reserved for future issuance under our 2016 Equity Incentive Plan and we will cease granting awards under our 2008 Equity Incentive Plan. Our 2016 Equity Incentive Plan and 2016 Employee Stock Purchase Plan will also provide for automatic annual increases in the number of shares reserved under the plans each year, as more fully described in the section entitled "Executive compensation—Employee benefit and stock compensation plans."

Unless otherwise noted, all information contained in this prospectus reflects and assumes the following:

- the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2016 into an aggregate of 10,360,419 shares of common stock immediately prior to the closing of this offering, which our stockholders approved on September 20, 2016;
- pursuant to their terms, the automatic net exercise of outstanding warrants to purchase 24,550 shares of preferred stock immediately prior to the closing of this offering, which will result in the issuance of 12,217 shares of common stock, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus;
- pursuant to their terms, the automatic conversion of outstanding warrants to purchase 60,786 shares of preferred stock into warrants to purchase 60,786 shares of common stock upon the closing of this offering;
- no exercise of a warrant, issued to Pacific Western Bank in September 2016, to purchase that number of shares of our Series E convertible preferred stock, at a purchase price of $8.2932 per share, equal to 3.0% of the total additional amount of debt drawn under our loan and security agreement (up to $5.0 million) divided by the purchase price, which will only be exercisable in the event that we borrow such additional amount and which will automatically convert to a warrant to purchase the same number of shares of common stock immediately prior to the closing of this offering pursuant to its terms;
- no exercise of the outstanding options or warrants other than as described above;
- a 2.9-to-1 reverse stock split, which became effective on September 23, 2016;
- the filing and effectiveness of our restated certificate of incorporation in Delaware and the adoption of our restated bylaws, both of which will occur immediately prior to the closing of this offering;
- no exercise by the underwriters of their option to purchase additional shares of our common stock; and
- no purchases by existing stockholders or their affiliates pursuant to the directed share program.

SUMMARY CONSOLIDATED FINANCIAL DATA

The summary consolidated statements of operations data presented below for the years ended December 31, 2014 and 2015 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated statements of operations data for the six months ended June 30, 2015 and 2016 and our consolidated balance sheet data as of June 30, 2016 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements were prepared on a basis consistent with our audited financial statements and reflect, in the opinion of management, all adjustments of a normal recurring nature that are necessary for the fair presentation of the financial statements. Our historical results are not necessarily indicative of the results that may be expected in any future period, and the results for the six months ended June 30, 2016 are not necessarily indicative of results to be expected for the full year ending December 31, 2016, or any other period.

The following summary consolidated financial data should be read with "Selected consolidated financial data," "Management's discussion and analysis of financial condition and results of operations" and our consolidated financial statements and related notes included elsewhere in this prospectus. The summary consolidated financial data in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this prospectus.

	Year ended December 31,		Six months ended June 30,	
	2014	2015	2015	2016
			(unaudited)	
	(in thousands, except shares and per share data)			
Consolidated statements of operations data:				
Revenue:				
Revenue	$ 1,683	$ 216	$ 224	$ —
Revenue, related party	1,856	3,823	1,739	1,848
Total revenue	3,539	4,039	1,963	1,848
Cost of revenue	2,912	2,503	1,205	1,294
Gross profit	627	1,536	758	554
Operating expenses:				
Research and development	5,767	12,978	5,968	5,098
Selling, general and administrative	4,700	3,491	1,679	2,975
Total operating expenses	10,467	16,469	7,647	8,073
Loss from operations	(9,840)	(14,933)	(6,889)	(7,519)
Interest expense, net	(220)	(549)	(263)	(290)
Gain (loss) from change in fair value of warrant liability	167	(34)	11	119
Other income (expense), net	3	(41)	(16)	(22)
Net loss	(9,890)	(15,557)	(7,157)	(7,712)
Other comprehensive income	9	5	10	4
Net loss and comprehensive loss	$ (9,881)	$ (15,552)	$ (7,147)	$ (7,708)
Net loss per share, basic and diluted(1)	$ (18.61)	$ (27.14)	$ (12.51)	$ (13.37)
Weighted-average common shares outstanding, basic and diluted(1)	531,430	573,181	572,195	576,757
Pro forma net loss per share, basic and diluted (unaudited)(1)		$ (1.72)		$ (0.81)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)(1)		9,026,927		9,691,211

(footnotes on following page)

(1) See Notes 2 and 4 to our audited consolidated financial statements and Notes 2 and 4 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the shares used in computing basic and diluted net loss per share and basic and diluted pro forma net loss per share.

	As of June 30, 2016		
	Actual	Pro forma(1)	Pro forma as adjusted(2)
		(unaudited) (in thousands)	
Consolidated balance sheet data:			
Cash and cash equivalents and short-term investments	$ 18,282	$ 18,282	$ 85,632
Working capital	13,924	13,924	81,274
Total assets	20,071	20,071	87,421
Term loan	9,883	9,883	9,883
Warrant liability	213	—	—
Convertible preferred stock	70,498	—	—
Accumulated deficit	(63,854)	(63,973)	(63,973)
Total stockholders' (deficit) equity	(62,690)	8,021	75,371

(1) The pro forma consolidated balance sheet data give effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2016 into an aggregate of 10,360,419 shares of common stock immediately prior to the closing of this offering; (ii) the automatic net exercise of outstanding warrants to purchase 24,550 shares of preferred stock immediately prior to the closing of this offering, which will result in the issuance of 12,217 shares of common stock, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the related reclassification of the warrant liability to stockholders' equity; and (iii) the automatic conversion of outstanding warrants to purchase 60,786 shares of preferred stock into warrants to purchase 60,786 shares of common stock upon the closing of this offering and the related reclassification of the warrant liability to additional paid-in capital.

(2) The pro forma as adjusted balance sheet data give effect to: (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 5,000,000 shares of common stock in this offering, at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of our pro forma as adjusted cash and cash equivalents and short-term investments, working capital, total assets and total stockholders' equity by approximately $4.7 million, assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us. Similarly, each increase (decrease) of one million shares in the number of shares offered would increase (decrease) each of our pro forma as adjusted cash and cash equivalents and short-term investments, working capital, total assets and total stockholders' equity by approximately $14.0 million, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions payable by us. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

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 prospectus, including our financial statements and the related notes appearing at the end of this prospectus. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, results of operations, financial condition and cash flows. If that were to happen, the trading price of our common stock could 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 $10.6 million. We have incurred significant losses in each period since our inception in 2008, with net losses of $9.9 million, $15.6 million and $7.7 million for the years ended December 31, 2014 and 2015 and the six months ended June 30, 2016, respectively. As of June 30, 2016, we had an accumulated deficit of approximately $63.9 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop and seek 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 prepare for and commence U.S. commercialization of our product, including the development 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 for 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 will 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;
- 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 expect to begin 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 and gastroenterologists, and, over time, to 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. 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, or design flaws in, our products. 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 or the small intestines, the patient could be severely injured. 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 subsequent surgery. 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. For example, physicians may 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.

In connection with the sale of over 23,000 units of our earlier generation Obalon balloon systems in international markets through June 30, 2016, nine SADEs have been reported to us, of which six were related to balloon deflations resulting in migration requiring surgical removal and three were 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. In one instance, a balloon was inflated inside a patient's esophagus, and following a subsequent surgical procedure intended to address esophageal injury, the patient died of sepsis. While we have evidence that the inflation occurred due to the physician's failure to follow our instructions and protocols for proper device placement, we have been unable to obtain sufficient information from the physician to verify the exact cause of injury, and we cannot guarantee that other similar improper inflations will not occur in the future.

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, and no experience with sales and marketing in the United States. 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 we plan to launch the product with a direct sales force that we are currently in the process of building. 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. 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 operations. 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 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 will be targeted at bariatric surgeons and gastroenterologists. These physicians 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 to date have occurred internationally using an earlier generation of the Obalon balloon system. We expect to transition our international sales to the current generation of the Obalon balloon system in 2017. As a result, we have no experience in manufacturing our 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 our cash and cash equivalents and short-term investments as of June 30, 2016 are not sufficient to fund our operations for the next 12 months. However, we believe that the net proceeds from this offering, 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 for at least two years following this offering. We expect our costs and expenses to increase in the future as we prepare for and commence U.S. commercialization of our Obalon balloon system, including the development 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 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 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 establishing 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 following our initial public offering 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 and all of our current revenue is 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 first six months ended June 30, 2016 and a majority of our total revenue for the year ended December 31, 2015. Although we intend to commence sales in the United States through a directed sales force, we expect Bader will continue to be a significant source of our revenue for the near term. While we have a contract with Bader that provides for certain minimum purchase requirements over the term of the agreement, restricts Bader's ability to sell competing products and limits Bader's ability to terminate the agreement, Bader may still devote insufficient resources to our products, sell competitive products or terminate its relationship with us. We also 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 intragastric balloon filled with saline. 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. 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.

In addition, the lease for our principal executive offices and manufacturing facility expires in March 2017, and while we are currently discussing an extension of the lease with the landlord, there can be no assurance that the current lease will be extended, modified, or replaced by a new lease facility prior to its expiration. Failure to satisfy our facility needs could have a detrimental impact on our ability to continue day to day operations and our business and future growth prospects could be harmed.

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. For example, we recently hired our Chief Financial Officer, Vice President of Sales and Vice President of Marketing and Vice President of Quality Assurance. We could experience disruptions as each of these individuals begins to integrate into the business and build his or her respective departments. Alternatively, our President and Chief Executive Officer, Andrew Rasdal, has

been with us since inception and has been instrumental in building operational capabilities, raising capital and guiding product development and regulatory strategy. In addition, our Vice President of Research and Development, Mark Brister, has led most of our product development activities, and our Vice President of Regulatory and Clinical Affairs, Amy VandenBerg, has been with us since inception and led our efforts to obtain FDA approval. If Andrew Rasdal was no longer working at our company, our industry credibility and operational capabilities would be harmed. Alternatively, if Mark Brister was no longer working at our company, our product development would be harmed, and if Amy VandenBerg was no longer with our company, our efforts to obtain FDA approval of future products and product improvements may be harmed. We do not currently maintain key personnel life insurance policies on any of our employees, including Andrew Rasdal, Mark Brister or Amy VandenBerg.

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.

In our SMART trial, 90.8% of patients who received the Obalon balloon system experienced an event that the FDA classifies as an adverse device event, or ADE. A substantial majority (82.3%) of the ADEs were considered mild in severity and required no medical intervention beyond homeopathic or over-the-counter medications, with the most common ADEs being abdominal pain, nausea and vomiting. Approximately 17.3% of the ADEs required prescription medications for medical management and the remaining 0.4% of ADEs were considered severe and required intervention beyond prescription medications. Only one ADE (0.08%) was considered a SADE, and involved a patient who developed peptic ulcer disease after receiving an outpatient total knee replacement that required the patient to receive NSAID and aspirin therapy during balloon treatment. NSAIDS are contraindicators during our balloon treatment.

In addition, as of June 30, 2016, we had sold over 23,000 units of our earlier generation Obalon balloon system in international markets. In our commercial experience, nine SADEs 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 international SADEs occurred in patients where the device was not used in accordance with approved labeling.

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.

As of June 30, 2016, we had $10.0 million in principal and interest outstanding under our loan and security agreement with Pacific Western Bank (as successor in interest to Square 1 Bank). Subsequent to June 30, 2016, we amended our loan and security agreement, pursuant to which an additional $5.0 million is available to us, none of which is outstanding. We are required to make interest-only monthly payments on the outstanding debt through March 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.

If we experience warranty claims 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 will be 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, 2015, we had federal, state and foreign tax net operating loss carryforwards, or NOLs, of approximately $31.5 million, $13.9 million and $1.3 million, respectively. Each of the federal and state NOLs will begin expiring in 2028, unless previously utilized. The foreign NOLs will begin expiring in 2023, unless previously utilized. We also had federal and California research and development tax credit carryforwards totaling $1.3 million and $1.1 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 our Obalon balloon system is dependent on the successful development and commercialization of future devices such as the EzPz inflation system, our next generation inflation system that is expected to replace the EzFill inflation system to inflate the balloon

with gas. Additionally, we are evaluating our vegetable-based HydroxyPropylMethylCellulose, or HPMC, capsule, which is expected to replace the current animal-based gelatin capsule. The primary information to support the EzPz inflation system and HPMC capsule is anticipated to be in vitro testing including but not limited to software validation, human factors assessment, and biocompatibility evaluation of the capsule. It is not anticipated that human clinical data will be required to support these regulatory submissions; however, it is possible that the FDA may require this information, which could delay potential approval. To support this potential request we are also evaluating these products in our current SMARTCAR study. While we expect to successfully complete the in vitro testing required to submit a PMA supplement for both the EzPz inflation system and the HPMC capsule, 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 EzPz inflation system or the HPMC capsule in the United States. Although we have collected preliminary data on these two products from our SMARTCAR trial, this preliminary data may not be predictive of its final results and failure of the trial can occur at any time. A number of companies in the medical device field have suffered significant setbacks during clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising preliminary results. Because we are depending on EzPz inflation system and HPMC capsule to achieve our revenue goals in future years, failure to successfully complete the study and receive FDA approval, 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 EzPz inflation system and the HPMC capsule as planned, our financial results could be harmed.

Failure to successfully complete our SMARTCAR clinical study if required by the FDA could impair our financial results. Such a failure could delay or prevent EzPz inflation system and/or HPMC capsule from obtaining regulatory approval, could require us to perform another clinical trial, which would be expensive, may not be successful and will significantly delay our ability to commercialize the EzPz inflation system and/or HPMC capsule, and could impair our ability to convince physicians of the benefits of our Obalon balloon system.

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's QSR, 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 June 30, 2016, we held 13 issued U.S. patents and had 18 pending U.S. patent applications, as well as 17 international patents issued in Europe, Mexico, Australia, Canada, Asia, China and Israel and 37 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 recently 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 THIS OFFERING AND OWNERSHIP OF OUR COMMON STOCK

Our common stock has never been publicly traded, and an active trading market may not develop or be sustained following this offering.

There is currently no public market for our common stock. Although we have applied to list our common stock on The NASDAQ Global Market, or NASDAQ, an active public trading market may not develop after completion of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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 initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary substantially from the market price of our common stock following this offering. The public trading price for our common stock after this offering will be 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, including our SMARTCAR trial;
- unanticipated or serious safety concerns related to the use of any of our 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. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price of shares of our common stock after this offering does not ever exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a return.

Our management will have considerable discretion in the application of the net proceeds that we receive from this offering, including for any of the purposes described in the section entitled "Use of proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering for the commercialization of our Obalon balloon system, continued research and development efforts and working capital and other general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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 will depend 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.

New investors purchasing our common stock in this offering will experience immediate and substantial dilution in the net tangible book value of their investment.

Our initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately prior to this offering. Therefore, if you purchase common stock in this offering, you will incur immediate dilution of approximately $10.28 in pro forma as adjusted net tangible book value per share as of June 30, 2016 from the price you paid, based on the assumed initial public offering price of $15.00 per share, the mid-point of the range set forth on the cover page of this prospectus. In the past, we have also issued options and warrants to acquire common stock at prices below the initial public offering price. To the extent outstanding options and warrants are ultimately exercised, there will be further dilution to investors who purchase shares in this offering. In addition, if the underwriters exercise their option to purchase additional shares or if we issue additional equity securities, investors purchasing shares in this offering will experience additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see “Dilution.”

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Based on shares outstanding as of June 30, 2016, upon completion of this offering, we will have outstanding a total of 15,953,471 shares of common stock. Of these shares, only the 5,000,000 shares of common stock sold in this offering by us, or 5,750,000 shares if the underwriters exercise their option to purchase additional shares in full, will be freely tradable, without restriction, in the public market immediately after this offering (excluding any shares purchased by our directors and executive officers pursuant to the directed share program or participants in our directed share program who purchase $1,000,000 or more of shares of our common stock that will be subject to lock-up agreements and shares purchased by certain significant stockholders that will be subject to Rule 144 resale restrictions). Each of our officers and directors and the holders of more than 95% of our capital stock have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. However, our underwriters may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of June 30, 2016, up to an additional 10,953,471 shares of common stock will be eligible for sale in the public market, approximately 7,473,472 of which are held by our officers, directors and their affiliated entities, and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, and various vesting agreements. In addition, 1,767,690 shares of our common stock that are subject to outstanding options as of June 30, 2016 and 229,528 shares of our common stock that are

subject to options granted after June 30, 2016 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act.

After this offering, the holders of an aggregate of 10,849,593 shares of our outstanding common stock as of June 30, 2016 will have 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 will be able to be sold freely in the public market upon issuance, subject to the 180-day lock-up period under the lock-up agreements described above and in the section entitled "Underwriting."

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 this offering; (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;
- being permitted to present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure in this prospectus;
- 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 have taken advantage of reduced reporting burdens in this prospectus. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation information that would be required if we were not an emerging growth company. 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 will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

As a public company, particularly after we are no longer an emerging growth company, we will 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 need 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 will continue to exercise significant influence over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

As of August 31, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 79.1% of our capital stock and, upon the closing of this offering, that same group will hold approximately 55.4% of our outstanding capital stock (assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any members of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering.

As a result, this group of stockholders will have the ability to control us through this ownership position even if they do not purchase any additional shares in this offering. 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 certificate of incorporation and our bylaws that will become effective immediately prior to the closing of this offering may 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. See the section entitled "Description of capital stock."

Our restated certificate of incorporation will designate 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 that will become effective immediately prior to the closing of this offering will provide 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 credit 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.

Special note regarding forward-looking statements

This prospectus, including the sections entitled "Prospectus summary," "Risk factors," "Use of proceeds," "Management's discussion and analysis of financial condition and results of operations" and "Business," 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 prospectus. 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 prospectus to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Market and industry data

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate is based on information from various sources, including independent industry publications. In presenting this information, we have also made assumptions based on such data and other similar sources, and on our knowledge of, and our experience to date in, the potential markets for our product. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled "Risk factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Use of proceeds

We estimate that the net proceeds from our sale of 5,000,000 shares of common stock in this offering at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $67.4 million, or $77.8 million if the underwriters exercise their option to purchase additional shares in full.

A $1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) the net proceeds to us from this offering by approximately $4.7 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions payable by us. Similarly, each increase (decrease) of one million shares in the number of shares offered would increase (decrease) the net proceeds to us from this offering by approximately $14.0 million, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions payable by us.

We currently intend to use the net proceeds we receive from this offering as follows:

- approximately $33.0 million to $40.0 million for the commercialization of our Obalon balloon system, including $30.0 million to $35.0 million for the development of our sales and marketing infrastructure and $3.0 million to $5.0 million for the expansion of our manufacturing facilities;
- approximately $13.0 million to $15.0 million for continued research and development efforts; and
- the remaining for working capital and other general corporate purposes.

We estimate that the net proceeds from this offering, 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 for at least two years following this offering. In the future, we 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.

This expected use of net proceeds of this offering represents our current intentions based upon our present plans and business conditions. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend upon a number of factors, including future sales growth, success of research and product development efforts, cash generated from future operations and actual expenses to operate our business. We may use a portion of the net proceeds to acquire complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

Pending their use as described above, we intend to invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government.

Dividend policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends. In addition, under our loan and security agreement with Pacific Western Bank (as successor in interest to Square 1 Bank), we are restricted from paying any dividends or making any distributions on account of our capital stock. See "Management's discussion and analysis of financial condition and results of operations—Liquidity and capital resources" for a description of the restrictions on our ability to pay dividends.

Capitalization

The following table sets forth our cash and cash equivalents and short-term investments and total capitalization as of June 30, 2016:

- on an actual basis;
- on a pro forma basis to give effect to: (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2016 into an aggregate of 10,360,419 shares of common stock immediately prior to the closing of this offering; (ii) the automatic net exercise of outstanding warrants to purchase 24,550 shares of preferred stock immediately prior to the closing of this offering, which will result in the issuance of 12,217 shares of common stock, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the related reclassification of the warrant liability to stockholders' equity; (iii) the automatic conversion of outstanding warrants to purchase 60,786 shares of preferred stock into warrants to purchase 60,786 shares of common stock upon the closing of this offering and the related reclassification of the warrant liability to additional paid-in capital; and (iv) the effectiveness of our restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give effect to: (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 5,000,000 shares of common stock in this offering, at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma information set forth in the table below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

You should read this table together with "Use of proceeds," "Selected consolidated financial data," "Management's discussion and analysis of financial condition and results of operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2016		
	Actual	Pro forma	Pro forma as adjusted[1]
	(unaudited) (in thousands, except shares and per share data)		
Cash and cash equivalents and short-term investments	$ 18,282	$ 18,282	$ 85,632
Term loan	9,883	9,883	9,883
Warrant liability	213	—	—
Convertible preferred stock, $0.001 par value; 34,460,759 shares authorized, 10,096,639 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	70,498	—	—
Stockholders' (deficit) equity:			
Preferred stock, par value $0.001; no shares authorized, issued and outstanding, actual and pro forma; 10,000,000 shares authorized and no shares issued and outstanding, pro forma as adjusted	—	—	—
Common stock, $0.001 par value; 45,000,000 shares authorized, 580,835 shares issued and outstanding, actual; 300,000,000 shares authorized, 10,953,471 shares issued and outstanding, pro forma; 15,953,471 shares issued and outstanding, pro forma as adjusted	1	11	16
Additional paid-in capital	1,159	71,979	139,324
Other comprehensive income	4	4	4
Accumulated deficit	(63,854)	(63,973)	(63,973)
Total stockholders' (deficit) equity	(62,690)	8,021	75,371
Total capitalization	$ 17,904	$ 17,904	$ 85,254

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents and short-term investments, additional paid-in capital, total stockholders' equity and total capitalization by approximately $4.7 million, assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions payable by us. Similarly, each increase (decrease) of one million shares in the number of shares offered would increase (decrease) each of cash and cash equivalents and short-term investments, additional paid-in capital, total stockholders' equity and total capitalization by approximately $14.0 million, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions payable by us.

The table above excludes the following shares:

- 1,767,690 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2016, with a weighted-average exercise price of $1.41 per share;
- 229,528 shares of common stock issuable upon the exercise of stock options granted after June 30, 2016, with an exercise price of $2.82 per share;

- 60,786 shares of common stock issuable upon the exercise of warrants to purchase shares of preferred stock outstanding as of June 30, 2016, with a weighted-average exercise price of $7.40 per share, which will become warrants to purchase 60,786 shares of common stock upon the closing of this offering; and
- 3,436,415 shares of common stock reserved for future issuance under our stock-based compensation plans as of June 30, 2016, consisting of (i) 1,056,415 shares of common stock reserved for future issuance under our 2008 Equity Incentive Plan as of June 30, 2016, which was reduced to 447,719 shares on July 17, 2016, (ii) 2,200,000 shares of common stock reserved for future issuance under our 2016 Equity Incentive Plan, which will become effective on the date immediately prior to the effective date of the registration statement of which this prospectus is a part, and (iii) 180,000 shares of common stock reserved for future issuance under our 2016 Employee Stock Purchase Plan, which will become effective on the effective date of the registration statement of which this prospectus is a part.

Dilution

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of June 30, 2016, our historical net tangible book value (deficit) was $(62.7) million, or $(107.93) per share of our common stock. Net tangible book value (deficit) per share represents our total tangible assets (total assets less intangible assets) less total liabilities and preferred stock, divided by the total number of our outstanding shares of common stock.

Our pro forma net tangible book value as of June 30, 2016 was approximately $8.1 million, or $0.73 per share of common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets (total assets less intangible assets) less total liabilities, divided by the total number of outstanding shares of our common stock, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2016 into an aggregate of 10,360,419 shares of common stock immediately prior to the closing of this offering; (ii) the automatic net exercise of outstanding warrants to purchase 24,550 shares of preferred stock immediately prior to the closing of this offering, which will result in the issuance of 12,217 shares of common stock, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

After giving effect to (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 5,000,000 shares of common stock in this offering, at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2016 would have been approximately $75.4 million, or $4.72 per share of our common stock. This represents an immediate increase in pro forma net tangible book value of approximately $3.99 per share to our existing stockholders and an immediate dilution of $10.28 per share to investors purchasing shares in this offering, as follows:

Assumed initial public offering price per share		$15.00
Pro forma net tangible book value per share as of June 30, 2016 before giving effect to this offering	$0.73	
Increase in pro forma net tangible book value per share attributable to this offering	3.99	
Pro forma as adjusted net tangible book value per share after this offering		4.72
Dilution in pro forma as adjusted net tangible book value per share to new investors participating in this offering		$10.28

A $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by approximately $0.29 and the dilution per share to new investors participating in this offering would increase (decrease) by approximately $0.71, assuming the number of shares offered, as set forth on the cover page of this

prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions payable by us. We may also increase or decrease the number of shares we are offering. A one million share increase in the number of shares offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by approximately $0.54 and the dilution per share to new investors participating in this offering would decrease by approximately $0.54, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions payable by us. Similarly, a one million share decrease in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value per share after this offering by approximately $0.62 and the dilution per share to new investors participating in this offering would increase by approximately $0.62, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions payable by us.

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be approximately $5.14 per share, and the dilution in pro forma as adjusted net tangible book value per share to new investors participating in this offering would be $9.86 per share.

The following table summarizes, on a pro forma as adjusted basis as of June 30, 2016, the differences between the number of shares of common stock purchased from us, the total cash consideration and the average price per share paid to us by existing stockholders and by new investors purchasing shares in this offering, at an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percent	
Existing stockholders	10,953,471	68.7%	$ 71,963,417	49.0%	$ 6.57
New investors participating in this offering	5,000,000	31.3	75,000,000	51.0	$15.00
Total	15,953,471	100%	$146,963,417	100%	

A $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share of our common stock, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors participating in this offering by approximately $5.0 million, assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same, and before deducting the estimated underwriting discounts and commissions payable by us. Similarly, each increase (decrease) of one million shares in the number of shares offered would increase (decrease) the total consideration paid by new investors participating in this offering by approximately $15.0 million, assuming the assumed initial public offering price remains the same and before deducting the estimated underwriting discounts and commissions payable by us.

If the underwriters exercise their option to purchase additional shares in full, the number of shares of common stock held by existing stockholders will be reduced to 65.6% of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to 34.4% of the total number of shares of common stock to be outstanding after this offering.

To the extent that any outstanding options and warrants described below are exercised, investors will experience further dilution. Assuming the exercise of all of our outstanding options and warrants as of June 30, 2016, the number of shares of common stock held by existing stockholders would be increased

to 71.9% of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering would be reduced to 28.1% of the total number of shares of common stock to be outstanding after this offering. Additionally, the cash consideration paid to us by existing stockholders would be $74.9 million, or approximately 50.0%, of the total cash consideration, and the cash consideration paid to us by new investors purchasing shares in this offering would remain $75.0 million, or approximately 50.0%, of the total cash consideration. The average price per share paid to us by existing stockholders would be $5.86 and the average price per share paid to us by new investors would remain unchanged.

Certain of our stockholders and their affiliates, some of which are affiliated with our directors, have indicated an interest in purchasing shares of common stock in this offering with an aggregate value of approximately $20.0 million at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these parties as they will on any other shares sold to the public in this offering. The information set forth above does not reflect any potential purchase of any shares in this offering by such parties.

The number of shares of our common stock to be outstanding after this offering excludes:

- 1,767,690 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2016, with a weighted-average exercise price of $1.41 per share;
- 229,528 shares of common stock issuable upon the exercise of stock options granted after June 30, 2016, with an exercise price of $2.82 per share;
- 60,786 shares of common stock issuable upon the exercise of warrants to purchase shares of preferred stock outstanding as of June 30, 2016, with a weighted-average exercise price of $7.40 per share, which will become warrants to purchase 60,786 shares of common stock upon the closing of this offering; and
- 3,436,415 shares of common stock reserved for future issuance under our stock-based compensation plans as of June 30, 2016, consisting of (i) 1,056,415 shares of common stock reserved for future issuance under our 2008 Equity Incentive Plan as of June 30, 2016, which was reduced to 447,719 shares on July 17, 2016, (ii) 2,200,000 shares of common stock reserved for future issuance under our 2016 Equity Incentive Plan, which will become effective on the date immediately prior to the effective date of the registration statement of which this prospectus is a part, and (iii) 180,000 shares of common stock reserved for future issuance under our 2016 Employee Stock Purchase Plan, which will become effective on the effective date of the registration statement of which this prospectus is a part.

Selected consolidated financial data

The selected consolidated statements of operations data for the years ended December 31, 2014 and 2015 and the consolidated balance sheet data as of December 31, 2014 and 2015 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The selected consolidated statement of operations data for the six months ended June 30, 2015 and 2016 and the consolidated balance sheet data as of June 30, 2016 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements were prepared on a basis consistent with our audited financial statements and reflect, in the opinion of management, all adjustments of a normal recurring nature that are necessary for the fair presentation of the financial statements. Our historical results are not necessarily indicative of the results that may be expected in any future period, and the results for the six months ended June 30, 2016 are not necessarily indicative of results to be expected for the full year ending December 31, 2016, or any other period.

The following selected consolidated financial data should be read with "Management's discussion and analysis of financial condition and results of operations" and our consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated financial data in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this prospectus.

	Year ended December 31,		Six months ended June 30,	
	2014	2015	2015	2016
			(unaudited)	
	(in thousands, except shares and per share data)			
Consolidated statements of operations data:				
Revenue:				
Revenue	$ 1,683	$ 216	$ 224	$ —
Revenue, related party	1,856	3,823	1,739	1,848
Total revenue	3,539	4,039	1,963	1,848
Cost of revenue	2,912	2,503	1,205	1,294
Gross profit	627	1,536	758	554
Operating expenses:				
Research and development	5,767	12,978	5,968	5,098
Selling, general and administrative	4,700	3,491	1,679	2,975
Total operating expenses	10,467	16,469	7,647	8,073
Loss from operations	(9,840)	(14,933)	(6,889)	(7,519)
Interest expense, net	(220)	(549)	(263)	(290)
Gain (loss) from change in fair value of warrant liability	167	(34)	11	119
Other income (expense), net	3	(41)	(16)	(22)
Net loss	(9,890)	(15,557)	(7,157)	(7,712)
Other comprehensive income	9	5	10	4
Net loss and comprehensive loss	$ (9,881)	$ (15,552)	$ (7,147)	$ (7,708)
Net loss per share, basic and diluted(1)	$ (18.61)	$ (27.14)	$ (12.51)	$ (13.37)
Weighted-average common shares outstanding, basic and diluted(1)	531,430	573,181	572,195	576,757
Pro forma net loss per share, basic and diluted (unaudited)(1)		$ (1.72)		$ (0.81)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)(1)		9,026,927		9,691,211

(1) See Notes 2 and 4 to our consolidated financial statements and Notes 2 and 4 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the shares used in computing basic and diluted net loss per share and basic and diluted pro forma net loss per share.

Selected consolidated financial data

	As of December 31,		As of June 30, 2016
	2014	2015	(unaudited)
	(in thousands)		
Consolidated balance sheet data:			
Cash and cash equivalents and short-term investments	$ 19,244	$ 12,531	$ 18,282
Working capital	19,364	8,236	13,924
Total assets	20,719	14,221	20,071
Term loan	4,877	9,841	9,883
Warrant liability	56	332	213
Convertible preferred stock	54,826	54,699	70,498
Accumulated deficit	(40,585)	(56,142)	(63,854)
Total stockholders' deficit	(39,856)	(55,139)	(62,690)

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 financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

OVERVIEW

We are a commercial-stage 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 swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients. We recently received premarket approval from the U.S. Food and Drug Administration, or 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. 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. We anticipate commencing the U.S. commercial launch of our Obalon balloon system in early 2017. As of June 30, 2016, we had sold over 23,000 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 Europe in the third quarter of 2012, and we expanded sales into Mexico and the Middle East in the third quarter of 2013. Our Obalon balloon system was sold in Europe through distributors, in Mexico directly to physicians and in the Middle East through a single distributor. In 2015, we discontinued sales in Europe and Mexico to conserve financial resources while we focused on developing our current Obalon balloon system and subsequently obtaining regulatory approval to market it in the United States, which we believe to be our largest single market opportunity. In 2017, we intend to discontinue international distribution of our earlier generation product and begin selling our current Obalon balloon system.

In June 2013, we entered into a distribution agreement with Bader Sultan & Bros. Co W.L.L., or 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, 2014 and 2015 totaled $1.9 million and $3.8 million, which represent 52.4% and 94.7% of total revenue, respectively. As of June 30, 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 as we commence commercial sales in the United States in 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 are building a direct sales organization consisting of regional sales directors, executive account managers and product specialists. We initially plan to sell the Obalon balloon system on a self-pay basis into existing physician specialty areas with weight loss practices, such as bariatric surgeons and gastroenterologists. Given the initial focus of our sales and marketing efforts, we believe we can begin targeting the U.S. market with a sales organization of approximately 15 to 20 individuals.

We generated total revenue, including revenue recognized from related parties, of $3.5 million, $4.0 million and $1.8 million for the years ended December 31, 2014 and 2015 and the six months ended June 30, 2016, respectively. For the years ended December 31, 2014 and 2015, our net loss was $9.9 million and $15.6 million, respectively, and for the six months ended June 30, 2016, our net loss was $7.7 million. We have not been profitable since inception, and as of June 30, 2016, our accumulated deficit was $63.9 million. Since inception, we have financed our operations primarily through private placements of our preferred securities and, to a lesser extent, debt financing arrangements. We expect to continue to incur net losses for the foreseeable future as we commercialize our product in the United States, including building our sales and marketing organization and expanding our manufacturing facilities, continue research and development efforts, and seek regulatory approval for new products and product enhancements. We will need additional funding to pay expenses relating to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed 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 Europe and Mexico, 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 Europe and Mexico, and as of June 30, 2016, total revenue consisted of sales of our Obalon balloon system to Bader in the Middle East.

We plan to focus on 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 produce our products and the manufacturing overhead that directly support production. Currently, a significant portion of our cost of revenue consists of manufacturing overhead, which is mostly fixed in nature. These overhead costs include the cost of compensation for operations supervision and management,

material procurement, inventory control, facilities and depreciation on production equipment. We expect cost of revenue to increase in absolute dollars to the extent our total revenue grows.

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 spread 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 and adopt new manufacturing processes and technologies.

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 expect to grow our sales and marketing force significantly in the near future in preparation for the commercial launch of our Obalon balloon system in the United States in early 2017. As a result, we expect SG&A expenses to significantly increase in absolute dollars and as a percentage of total revenue for the foreseeable future as we 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 becoming a public company.

RESULTS OF OPERATIONS

	Year ended December 31,		Six months ended June 30,	
	2014	2015	2015	2016
	(in thousands)			
Consolidated statements of operations data:				
Revenue:				
Revenue	$ 1,683	$ 216	$ 224	$ —
Revenue, related party	1,856	3,823	1,739	1,848
Total revenue	3,539	4,039	1,963	1,848
Cost of revenue	2,912	2,503	1,205	1,294
Gross profit	627	1,536	758	554
Operating expenses:				
Research and development	5,767	12,978	5,968	5,098
Selling, general and administrative	4,700	3,491	1,679	2,975
Total operating expenses	10,467	16,469	7,647	8,073
Loss from operations	(9,840)	(14,933)	(6,889)	(7,519)
Interest expense, net	(220)	(549)	(263)	(290)
Gain (loss) from change in fair value of warrant liability	167	(34)	11	119
Other income (expense), net	3	(41)	(16)	(22)
Net loss	(9,890)	(15,557)	(7,157)	(7,712)
Other comprehensive income	9	5	10	4
Net loss and comprehensive loss	$ (9,881)	$(15,552)	$(7,147)	$(7,708)

Comparison of six months ended June 30, 2015 and 2016

Total revenue. Total revenue decreased $0.2 million to $1.8 million during the six months ended June 30, 2016, compared to $2.0 million during the six months ended June 30, 2015. This decrease was primarily attributable to a decrease in the volume sold as we discontinued sales of the Obalon balloon system in Europe and Mexico beginning in the third quarter of 2015.

Cost of revenue. Cost of revenue increased $0.1 million to $1.3 million during the six months ended June 30, 2016, compared to $1.2 million during the six months ended June 30, 2015. This increase was primarily attributable to changes in the allocation of production cost between R&D expense and cost of revenue.

Research and development expenses. R&D expenses decreased $0.9 million to $5.1 million during the six months ended June 30, 2016, compared to $6.0 million during the six months ended June 30, 2015. This decrease was primarily attributable to a $1.3 million decrease in clinical trial expenses due to the conclusion of our SMART trial. This decrease was partially offset by a $0.3 million increase in employee-related expenses associated with additional headcount and a $0.1 million increase due to payments to outside consultants associated with projects to prepare us for FDA audits during the six months ended June 30, 2016.

Selling, general and administrative expenses. SG&A expenses increased $1.3 million to $3.0 million during the six months ended June 30, 2016, compared to $1.7 million during the six months ended June 30, 2015. This increase was primarily attributable to a $1.0 million increase in legal fees associated with increased intellectual property development and protection and a $0.3 million increase in employee-related expenses from an increase in headcount.

Interest expense, net. Interest expense, net remained relatively consistent at $0.3 million for the six months ended June 30, 2015 and 2016.

Comparison of years ended December 31, 2014 and 2015

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 June 30, 2016, we had cash and cash equivalents and short-term investments of $18.3 million and an accumulated deficit of $63.9 million. Our primary sources of capital have been private placements of preferred stock and the incurrence of debt. To date, we have raised an aggregate of $70.5 million in proceeds from convertible preferred stock financings. Additionally, in June 2013, we incurred $3.0 million of debt under a loan and security agreement with Square 1 Bank, which was amended in October 2014 to increase the outstanding debt to $5.0 million with an additional $5.0 million funded in January 2015, which resulted in aggregate outstanding indebtedness as of June 30, 2016 of $10.0 million. In September 2016, the loan and security agreement was subsequently amended to provide for an additional $5.0 million in funding, which we may borrow at any time prior to March 7, 2017.

Due to the FDA's recent approval of our Obalon balloon system, we expect to incur substantial additional expenditures in the next 12 months to support the commercial launch of our product in the Unites States beginning in early 2017. We believe that cash and cash equivalents and short-term

investments as of June 30, 2016 are not sufficient to fund these operations for the next 12 months. However, we believe that the net proceeds from this offering, 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 for at least two years following this offering. We expect our costs and expenses to increase in the future as we prepare for and commence U.S. commercialization of our Obalon balloon system, including the development 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 establishing 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 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 following our initial public offering 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.

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 and September 2016.

As of June 30, 2016, we could borrow up to $10.0 million in two tranches of $5.0 million each. The first $5.0 million tranche allowed for an additional $2.0 million of outstanding debt and was funded upon execution of the amendment in October 2014. The second $5.0 million was available upon our receipt of at least $20.0 million in equity proceeds. In January 2015, following our Series D preferred stock offering, the full $5.0 million of the second tranche was funded. As of June 30, 2016, we had $10.0 million outstanding under this loan and security agreement, which had a variable annual interest rate equal to the greater of the prime rate plus 1.75% or 5.0%, and matured in October 2018.

Subsequent to June 30, 2016, we amended the loan and security agreement to allow for total borrowings up to $15.0 million in two tranches as follows: a first tranche consisting of $10.0 million funded in September 2016, of which the full $10.0 million was used to repay the existing debt with Pacific Western Bank (a successor in interest to Square 1 Bank) (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 current interest rate on the outstanding debt is a variable annual rate equal to the greater of the prime rate plus 1.50% or 5.0%. The loan and security agreement provides for an interest-only period through March 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 debt currently matures in September 2020, at which time all amounts outstanding, including accrued interest, become immediately due and payable.

Pursuant to the loan and security agreement, we issued to Pacific Western Bank a warrant to purchase a number of our shares of Series E convertible preferred stock, at a purchase price of $8.2932 per share, equal to 3.0% of the total amount of debt drawn under the second tranche divided by the purchase price, which will only be exercisable in the event that we borrow all or part of the second tranche.

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, if our total cash is less than $15.0 million, we are required to maintain all our deposits, transaction accounts and primary investment accounts with Pacific Western Bank, and if our total cash is greater than $15.0 million, we are required to maintain 50% of our deposits, transaction accounts and primary investment accounts with Pacific Western Bank.

CASH FLOWS

	Year ended December 31,		Six months ended June 30,	
	2014	2015	2015	2016
	(in thousands)			
Net cash (used in) provided by:				
Operating activities	$ (9,907)	$(11,392)	$(3,452)	$ (8,663)
Investing activities	(7,918)	2,777	(6,549)	(4,892)
Financing activities	22,188	5,062	5,059	14,528
Exchange rate effect	12	7	—	—
Net increase (decrease) in cash and cash equivalents	$ 4,375	$ (3,546)	$(4,942)	$ 973

Net cash used in operating activities

During the six months ended June 30, 2016, net cash used in operating activities was $8.7 million, consisting primarily of a net loss of $7.7 million and an increase in net operating assets of $1.2 million, primarily related to the payment of compensation accrued at December 31, 2015. These items were offset by non-cash charges of $0.2 million, consisting primarily of depreciation, stock-based compensation expense and non-cash interest expense related to amortization of investment premium and debt discount.

During the six months ended June 30, 2015, net cash used in operating activities was $3.5 million, consisting primarily of a net loss of $7.2 million, offset by a decrease in net operating assets of $3.3 million and non-cash charges of $0.4 million. The decrease in net operating assets consisted primarily of an increase in accrued expenses for our SMART trial and a customer deposit received from Bader. 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.

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.

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 (used in) provided by investing activities

During the six months ended June 30, 2016, net cash used in investing activities was $4.9 million, consisting primarily of purchases of short-term investments, partially offset by maturities of short-term investments.

During the six months ended June 30, 2015, net cash used in investing activities was $6.5 million, consisting primarily of purchases of short-term investments, partially offset by maturities 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.

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 six months ended June 30, 2016, net cash provided by financing activities was $14.5 million, consisting primarily of net proceeds of $14.5 million from the issuance of Series E convertible preferred stock.

During the six months ended June 30, 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, 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 Square 1 Bank. The following table sets out, as of December 31, 2015, 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)	$ 279	$ 225	$ 54	$ —	$ —
Term loan	10,000	833	9,167	—	—
Total	$10,279	$ 1,058	$ 9,221	$ —	$ —

(1) Consists of obligations under a multi-year, non-cancelable building lease for our facility in Carlsbad, California. The lease expires on March 31, 2017.

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 June 30, 2016, we had completed our lead clinical trial and all material expenses were accrued.

In September 2016, we amended our loan and security agreement with Pacific Western Bank. See "—Loan and security agreement."

Our contractual obligations as of June 30, 2016 have not otherwise significantly changed from December 31, 2015.

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 prospectus, 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. As of June 30, 2016, the product is sold to one customer, Bader, a related party and healthcare product distributor based in Sufat, Kuwait. We recognize revenue when the following revenue recognition 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, consultants and members of our board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

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 share-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.*** 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 this offering, our board of directors intends to determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

The intrinsic value of all outstanding options as of June 30, 2016 was $23.8 million based on the estimated fair value of our common stock of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

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.

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 IRC section 382 limitations on the use of our U.S. federal and state tax net operating loss carryforwards, such tax loss carryforwards have been removed from the deferred tax assets as of December 31, 2014 and December 31, 2015.

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 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 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.

JOBS ACT ACCOUNTING ELECTION

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

NEW 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 us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In May 2014, the FASB issued Accounting Standard Update, or ASU, 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. ASU 2014-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016. Entities are able to use one of three prescribed transition methods. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. We have not yet selected a transition method as we are currently evaluating the impact of the amended revenue recognition guidance on our consolidated financial statements.

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 fiscal years ending after December 15, 2016. We do not anticipate that the adoption of ASU 2014-15 will have a material impact on our consolidated financial statements.

In April 2015, FASB issued ASU 2015-03, *Interest – Imputation of Interest*. This simplifies the presentation of debt issuance costs by requiring them to be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability. ASU 2015-03 is effective for financial statements issued for fiscal years beginning after December 15, 2015. We previously presented debt issuance costs as a direct deduction from the carrying amount of its debt liabilities. As such, we have early adopted the provisions of ASU 2015-03 for the years ended December 31, 2014 and 2015.

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 fiscal years beginning after December 31, 2016 with earlier application permitted as of the beginning of an interim or annual reporting period. We do not expect that the adoption of this guidance will have a significant impact on our consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, an update to Accounting Standards Codification, or ASC, 740, *Income Taxes*. Current GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. For nonpublic business entities, the amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The FASB also decided to permit earlier application by all entities as of the beginning of any interim or annual reporting period. The FASB further provides that this update may be applied to all deferred tax liabilities and assets prospectively. We adopted this update prospectively beginning in the year ended December 31, 2015. No prior periods were retrospectively adjusted.

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 us on January 1, 2019, with early adoption permitted. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which involves several aspects of the accounting for share-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 share-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 us on January 1, 2017, with early adoption permitted. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents and short-term investments, which 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 June 30, 2016, our aggregate outstanding indebtedness was $10.0 million, which bears interest at the rate equal to the greater of the prime rate plus 1.75% or 5.0%. In September 2016, we entered into an amendment to the loan and security agreement which amended the rate 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, 2015 and June 30, 2016, 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.

Business

OVERVIEW

We are a commercial-stage 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 swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients. We recently received premarket approval, or PMA, from the U.S. Food and Drug Administration, or 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. 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. We anticipate commencing the U.S. commercial launch of our Obalon balloon system in early 2017. As of June 30, 2016, we had sold over 23,000 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. Having received PMA approval for the Obalon balloon system, we are currently focused on commencing U.S. commercialization using a direct sales force, which we anticipate will occur in early 2017.

Obesity is one of the largest, most debilitating, costly and underserved disease states globally. In adults, the disease is linked to several co-morbidities, including hypertension, type 2 diabetes, high blood pressure, certain cancers and other chronic conditions, 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. Current treatment alternatives for obese patients begin with lifestyle modification, such as diet and exercise. If this alternative fails to produce the desired results, physicians may prescribe pharmaceutical therapies, typically to obese or overweight patients with a lower body mass index, or BMI. Although pharmaceutical therapies have been effective in assisting with weight loss, they are often associated with safety risks and negative side effects that may limit patient compliance. In obese patients with a higher BMI, physicians may pursue aggressive surgical treatments, such as gastric bypass and gastric banding. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size; however, they present substantial side effects and carry short- and long-term safety risks that have limited adoption. Importantly, bariatric surgical procedures can result in permanent changes to the patient's anatomy, are often associated with significant reoperation rates, typically involve extended hospitalization and can result in patient intolerance to common foods.

Recently, new medical procedures have been introduced in an attempt to address the gap in care between pharmaceutical treatment and invasive surgical procedures. These new procedures have included neuroblocking therapy, aspiration therapy and traditional intragastric balloons. The traditional intragastric balloons currently available in the U.S. market were approved for use in 2015. These balloons are large, saline-filled silicone devices that must be both placed in the stomach and later removed with an endoscopic procedure performed under anesthesia. While in the stomach, the balloons fill space, creating a sense of fullness in the patient. Traditional intragastric balloons have been associated with successful weight loss. However, we believe traditional intragastric balloons suffer limitations that are impeding their adoption, including their rate of SADEs, a lack of comfort and tolerability, a limited ability to provide progressive and sustained weight loss and an inconvenient placement procedure.

We designed the Obalon balloon system to address many of the limitations of traditional intragastric balloons. We believe the Obalon balloon system offers patients and physicians the following benefits:

- ***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 June 2016, we had sold over 23,000 units of our earlier generation Obalon balloon systems in international markets and had only nine 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.*** Our Obalon balloon is filled with a proprietary mix of gas, as opposed to heavier saline solutions used in traditional intragastric balloons. Our system is designed to use three Obalon balloons over the course of treatment, allowing the volume in the stomach to be gradually increased. 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 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 entire six-month balloon treatment period, and maintained, on average, 89.5% of the weight loss 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 Obalon balloon. The balloon is attached to a microcatheter that enables inflation and then is detached from the Obalon balloon and removed from the patient. Placement typically occurs in less than ten minutes and patients can return to normal activity once the placement is complete. 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. We believe patients will benefit from lower treatment costs, no post-placement recovery period and a quick return to daily activities.

Based on the results of our double-blinded, randomized, sham-controlled SMART trial, we received PMA approval from the FDA in September 2016 for temporary use of our Obalon balloon system to facilitate weight loss in obese adults with a 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 trial results met or exceeded, and were statistically significant for, both of our co-primary endpoints.

In 2012, we began selling an earlier generation of our Obalon balloon system in a limited number of countries outside of the United States through a combination of direct sales efforts and distributors. In 2015, we refocused our efforts toward developing and seeking regulatory approval for our balloon system in the United States and discontinued most of our international sales efforts other than our sales to Bader Sultan & Bros. Co. W.L.L., or Bader, our distributor in the Middle East and one of our significant stockholders. We intend to focus our sales and marketing efforts primarily on selling our Obalon balloon system in the United States through a direct sales force. We initially plan to sell the Obalon balloon system on a self-pay basis to bariatric surgeons and gastroenterologists with existing weight loss practices. We believe the design features of the Obalon balloon system will enable us to penetrate these existing physician specialties and later expand into new specialties, such as plastic surgery.

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 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 intragastric balloons in the United States are the ReShape Duo Balloon and the ORBERA Balloon. While generally effective in delivering weight loss, these traditional intragastric balloons have been accompanied by a number of limitations that have impeded their adoption, including:

- ***Rate of SADEs.*** In the pivotal clinical trial for the ReShape Duo Balloon, 31 device- or procedure-related serious adverse events were reported in 20 patients, resulting in an SADE rate of approximately

7.5%. The most common SADEs were vomiting and abdominal pain. Similarly, in the pivotal clinical trial for the ORBERA Balloon, 17 serious adverse events were reported in 16 patients, resulting in an SADE rate of approximately 10%. The most significant SADE was severe and intolerable gastrointestinal upset.

- ***Lack of comfort and tolerability.*** The ReShape Duo Balloon consists of two attached balloons that are filled and sealed separately. Each balloon can hold a maximum of 450cc of saline solution. The ORBERA Balloon is a single balloon that can be filled to a range of 400cc to 700cc. Neither of these traditional balloon systems allows for the volume of its respective balloon to be adjusted after placement, nor can additional balloons be added after the initial placement. As a result, physicians cannot incrementally increase the volume of the balloons and, therefore, the patient begins treatment with the maximum volume. We believe that this, combined with the weight of the filled balloons, which tend to sink to the bottom of the stomach, contributes to a lack of patient comfort and tolerability.
- ***Limited ability to provide progressive and sustained weight loss.*** While clinical data generated from individual trials is not directly comparable due to differences of the clinical protocols of each trial, we have highlighted the differences for illustrative purposes. Patients in the pivotal trial for the ORBERA balloon lost only 31% of their total body weight loss, or approximately 6.8 lbs, in the last four months of use during the six-month treatment period, and mean weight loss for the six-month treatment period was 21.8 lbs. Additionally, six months after removal of the ORBERA Balloon, patients in ORBERA's pivotal trial regained 26% of the weight loss, or 5.6 lbs, resulting in a mean weight loss of 16.2 lbs at 12 months. For patients receiving balloon treatment in the ReShape pivotal trial, the mean weight loss at six months was 14.3 lbs. Furthermore, the average treatment subject in ReShape's pivotal trial with weight loss at six months regained 40% of the weight loss at one year, resulting in a mean weight loss of 9.9 lbs at 12 months.
- ***Inconvenient placement procedure.*** Both the ReShape Duo Balloon and the ORBERA Balloon procedures require both the device placement and device removal to be performed in an endoscopic procedure using anesthesia. The placement procedure for the ReShape Duo Balloon takes an average of approximately 20 minutes and for the ORBERA Balloon takes an average of approximately 30 minutes. The patient cannot immediately return to normal activities and must be placed under medical observation for a few hours until cleared to go home.

OUR SOLUTION

We have developed our Obalon balloon system to overcome the limitations of traditional 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 June 2016, we had sold over 23,000 units of our earlier generation Obalon balloon systems in international markets and had only nine 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 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 and gastroenterology.*** We plan to initially focus on direct sales to the leading bariatric surgeons and gastroenterologists 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. 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 plan to 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 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 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.
- ***Expand into new physician channels.*** Although our initial focus is on bariatric and gastroenterology practices where the physician has or is already developing the capability to provide weight loss treatments, we also plan to target additional physician specialties that have access to obese patients,

including the 1,900 aesthetically focused plastic surgeons. We believe that plastic surgeons are among the physicians that have access to patients appropriate for the Obalon balloon system, have experience managing self-pay centers and have the capability to learn and perform Obalon balloon placements.

- ***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 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.

Swallowable Capsule **EzFill Inflation System** **Gas-Filled Balloon**

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.

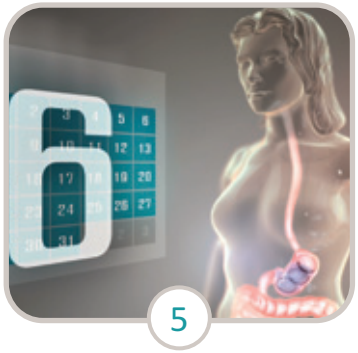
The following pictures depict the treatment steps of the Obalon balloon system:

The patient swallows a capsule attached to a microcatheter. No sedation or anesthesia is required.

The balloon capsule location is confirmed in stomach with digital imaging and EzFill inflation system. Balloon is inflated with gas.

Microcatheter is removed, leaving the inflated balloon behind.

Three balloons placed over 12 weeks to stimulate progressive weight loss and minimize side-effects.



After six-month treatment period, all balloons are removed in a short endoscopic procedure.

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 expect to submit a PMA supplement for the HPMC Obalon balloon capsule in the United States.

Next generation inflation system

Our next generation inflation system, the EzPz inflation system, is designed to be automated, simpler to operate and to provide more reliable and consistent Obalon balloon placements. The EzPz inflation system has Certificat de Conformité, or CE, mark approval and is approved in Brazil and select Middle East markets. We believe the EzPz inflation system will require a PMA supplement approval for use in the United States.

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 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 June 30, 2016, we had ten 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, 2014 and 2015 and for the six months ended June 30, 2016 were $5.8 million, $13.0 million and $5.1 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 nine clinical trials, which included a total of 630 patients as of June 30, 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.

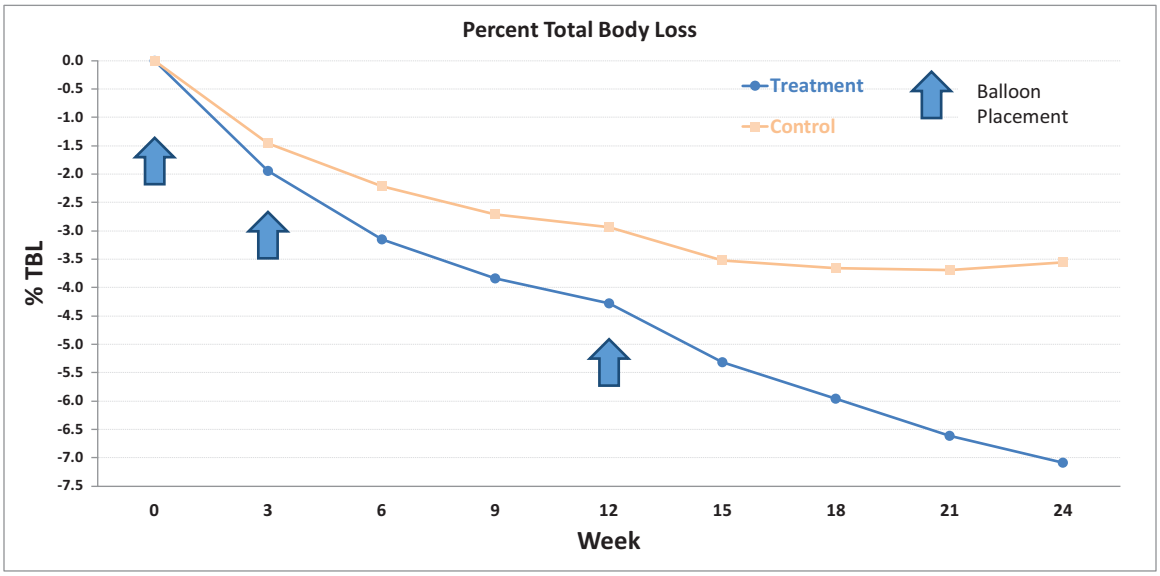
Main Analysis of -5% TBL Responder Rate	Estimate
Obalon Treatment Group—Per Protocol Cohort*	120 / 185 (64.9%)
Sham-Control Group	58 / 181 (32.0%)
Difference (Treatment less Control)	32.8%

* 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.

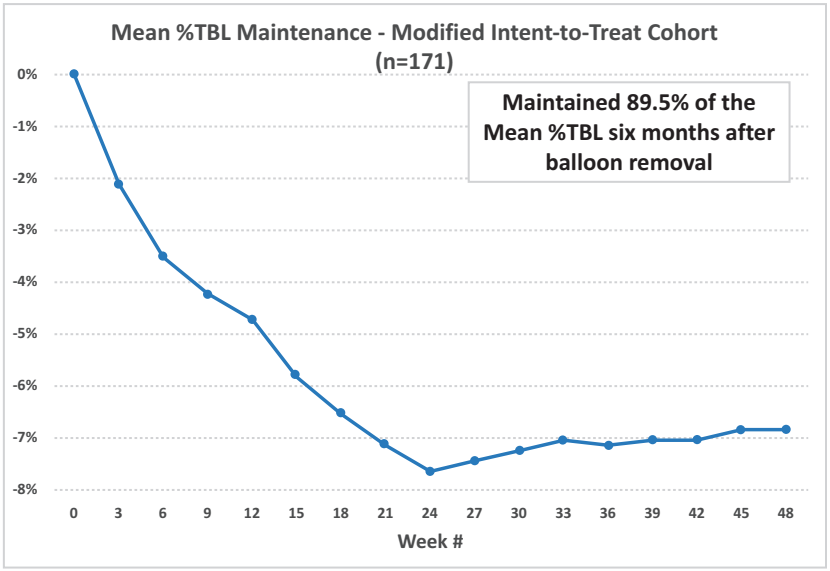


In addition, nearly all patients in the Obalon treatment group, including patients in the bottom 25% of the group, achieved TBL, EWL and weight loss and a reduction in BMI. The table below summarizes the mean, the average of the top 25% of the results, the average of the bottom 25% of the results and 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 June 2016, we had sold over 23,000 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.

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 have named SMARTCAR, to evaluate the safety and efficacy profile of our new HPMC vegetable-derived capsule and EzPz inflation system. We are currently enrolling patients for the trial at clinical sites in the United States. The data from the SMARTCAR trial are intended to be used to support our filing of a PMA supplement for our HPMC capsule for use with our Obalon balloon system.

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 10 to 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.

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 are building a direct sales organization consisting of regional sales directors, executive account managers and product specialists. Our sales team will encompass 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 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. Currently, Bader's minimum purchase obligation under the agreement for 2016 and 2017 is 7,500 and 12,000 balloon systems, respectively. The initial term of the agreement expires in December 2019, and will thereafter automatically renew for successive terms of 12 months, subject to certain exceptions. 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.

Our initial 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 and gastroenterology, 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. 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 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 June 30, 2016, we held 13 issued U.S. patents and had 18 pending U.S. patent applications, as well as 17 international patents issued in Europe, Mexico, Australia, Canada, Asia, China and Israel and 37 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 June 30, 2016, we held one registered U.S. trademark and eight registered marks in Europe, Asia and Mexico. We have three pending U.S. trademark applications and 11 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 from them, any of our supplies. 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 13 external audits, the last of which occurred in May 2016 and resulted in no Form 483 observations.

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

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 FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, 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.

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 2015 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 June 30, 2016, we had 51 employees, including 17 in manufacturing and operations, one in sales and marketing, ten in research and development, 16 in clinical affairs, regulatory affairs and quality assurance and seven in finance, general administrative and executive administration. All 51 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.

FACILITIES

Our principal executive offices are located in a 17,500 square foot facility Carlsbad, California. The term of the lease for our facility extends through March 2017, and we are currently discussing extension with our landlord. 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 and anticipated future needs through 2018.

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.

Management

EXECUTIVE OFFICERS AND DIRECTORS

The following table provides information regarding our executive officers and directors as of August 31, 2016:

Name	Age	Position
Executive Officers:		
Andrew Rasdal	58	President, Chief Executive Officer and Director
William Plovanic	47	Chief Financial Officer
Mark Brister	54	Vice President of Research and Development
Nooshin Hussainy	58	Vice President of Finance
Steve Johnson	58	Vice President of Operations
Lisa Metzner	47	Vice President of Marketing
Matthew Norwood	41	Vice President of Sales
Amy VandenBerg	41	Vice President of Regulatory and Clinical Affairs
Donald Young	58	Vice President of Quality Assurance
Non-Employee Directors:		
Kim Kamdar(1)(2)	49	Chairperson of the Board of Directors
Ray Dittamore(2)(3)	73	Director
Douglas Fisher(1)	40	Director
Les Howe(1)(3)	72	Director
Sharon Stevenson(3)	67	Director

(1) Member of the Nominating and Corporate Governance Committee
(2) Member of the Compensation Committee
(3) Member of the Audit Committee

EXECUTIVE OFFICERS

Andrew Rasdal has served as our President and Chief Executive Officer and a member of our board of directors since June 2008. Previously, Mr. Rasdal was the President and Chief Executive Officer at DexCom, Inc., a medical device company, from January 2002 until June 2007. Prior to DexCom, Mr. Rasdal served as President of Vascular and Senior Vice President for Medtronic, Inc., a medical technology development company, from 1999 to 2002. Prior to Medtronic, Mr. Rasdal served as Vice President of Marketing at Arterial Vascular Engineering, Inc., or AVE (acquired by Medtronic), a coronary stent company, from 1997 to 1999. Mr. Rasdal has also served in various senior positions at EP Technologies, Inc., SCIMED Life Systems, Inc. and Advanced Cardiovascular Systems, Inc. Mr. Rasdal holds a B.S. from San Jose State University and an M.M. from the Kellogg School of Management at Northwestern University. Our board of directors believes that Mr. Rasdal should serve as a director due to his deep understanding of our company and product and his significant experience in the medical technology industry.

William Plovanic has served as our Chief Financial Officer since March 2016. Previously, Mr. Plovanic served as Managing Director, Medical Technology Equity Research at Canaccord Genuity Inc., an investment bank, from February 2007 to March 2016. Prior to Canaccord Genuity, Mr. Plovanic served in various roles at First Albany Capital Inc. from February 2001 to February 2007, including as Managing Director, Equity Research. Mr. Plovanic holds a B.S. from Bradley University and is a CFA charterholder.

Mark Brister has served as our Vice President of Research and Development since June 2008. Prior to joining us, Mr. Brister served as the Vice President of Research and Development for DexCom from 2003 to 2008. Prior to DexCom, Mr. Brister served as Vice President Vascular Research and Development for Medtronic from 1999 to 2003. Prior to Medtronic, Mr. Brister served as Vice President of Research and Development and Director of Operations for Arterial Vascular Engineering from 1993 to 1999.

Nooshin Hussainy has served as our Vice President of Finance since December 2011. Prior to joining us, Ms. Hussainy served as the Vice President of Accounting and Corporate Controller at GenMark Diagnostics, Inc., a molecular diagnostics company, from April 2010 to September 2011. Prior to GenMark Diagnostics, Ms. Hussainy served as the Vice President of Accounting and Corporate Controller at ACTIVE Network, LLC, a worldwide registration software and advertising company, from 2008 to 2010. Ms. Hussainy previously served as the Corporate Controller at DexCom from 2003 to 2008 and at Entropia, Inc. from 2001 to 2003. Ms. Hussainy has also served as the Assistant Controller at Thermolase Corporation. Ms. Hussainy holds a B.A. from National University.

Steve Johnson has served as our Vice President of Operations since January 2014. Prior to joining us, Mr. Johnson served as the consulting Vice President of Operations at Silk Road Medical, a medical device company, from June 2013 to January 2014. Prior to Silk Road Medical, Mr. Johnson served as the Chief Operating Officer and Senior Vice President of Manufacturing and Product Development at iRhythm Technologies, Inc., a privately held digital health company from January 2011 to December 2012. Prior to iRhythm Technologies, Mr. Johnson served as Senior Vice President, Operations at Aptus Endosystems, Inc., a medical device company, from September 2008 to August 2009. Mr. Johnson has also served as the Senior Vice President, Operations and Vice President of Manufacturing at Heartport, Inc., as well as the Vice President of Manufacturing at Guident (acquired by Abbott Vascular). Mr. Johnson holds a B.S. from Kettering University.

Lisa Metzner has served as our Vice President of Marketing since June 2016. Prior to joining us, Ms. Metzner served as Senior Director, North America Marketing at ZELTIQ Aesthetics Inc., a medical technology company, from March 2013 to June 2016. Prior to ZELTIQ, Ms. Metzner served as Director, Aesthetics Consumer Marketing at Medicis Pharmaceutical Corporation (a division of Valeant Pharmaceuticals International, Inc.), a medical cosmetics company, from August 2011 to March 2013. Prior to Medicis, Ms. Metzner served as the Principal/Marketing Consultant at Rosas Consulting Group, LLC, a marketing and branding firm, from March 2009 to September 2011. Ms. Metzner has also served as the Senior Marketing Manager, Global Markets with ConAgra Foods, Inc., a food and consumer products company, from June 1998 to September 2006, and as the Senior Manager, Consumer Marketing with Allergan, Plc, a global pharmaceutical company, from September 2006 to February 2009. Ms. Metzner holds a B.A. from the University of Wisconsin-Whitewater and an M.B.A. from Pepperdine University.

Matthew Norwood has served as our Vice President of Sales since July 2016. Prior to joining us, Mr. Norwood served as Area Director of Sales at Merz North America, a medical products company, from November 2014 to July 2016. Prior to Merz, Mr. Norwood held various positions at Ulthera, Inc., a medical device company, from October 2010 to November 2014, including as the Sales Director and South Texas Territory Manager. Prior to Ulthera, Mr. Norwood also held various positions at Ethicon Inc., a subsidiary of Johnson & Johnson that designs medical devices, from February 2005 to October 2010, including as the Market Development Manager and the Senior Full Line Sales Representative. Prior to Ethicon, Mr. Norwood held various positions at Merck & Co., Inc., d.b.a Merck Sharp & Dohme, including as the Osteoporosis Specialty Representative and as a Professional Representative. Mr. Norwood holds a B.A. from Saint Edward's University.

Amy VandenBerg has served as our Vice President of Regulatory Affairs since February 2012 and assumed the position of Vice President of Clinical and Regulatory Affairs in November 2014. Ms. VandenBerg joined us in 2008 as Director of Regulatory Affairs. Prior to joining us, Ms. VandenBerg held positions of increasing leadership at other medical device companies, including DexCom and Cygnus, Inc. Ms. VandenBerg has more than 18 years of experience with a focus on medical device quality systems, clinical affairs as well as domestic and international regulatory affairs. Ms. VandenBerg holds a B.S. from St. Mary's College of California.

Donald Young has served as our Vice President of Quality Assurance since June 2016. Prior to joining us, Mr. Young served as Director of Quality Assurance and Regulatory Affairs at CareFusion Corporation (acquired by Becton Dickinson), a medical technology company that manufactures medical supplies, devices and lab equipment, from 2011 to 2016. Prior to CareFusion, Mr. Young served as Vice President of Quality Assurance and Regulatory Affairs at Flex Medical, a division of Flextronics International Ltd. (formerly Avail Medical Products, Inc. and Pacific Device Inc.) from 2000 to 2011 (and prior positions in quality assurance since 1990). Mr. Young holds a B.S. from Rutgers University (College of Engineering).

NON-EMPLOYEE DIRECTORS

Kim Kamdar, Ph.D. has served as a member of our board of directors since January 2008. Dr. Kamdar is currently a partner at Domain Associates, LLC, a venture capital firm, where she has worked since 2005. Prior to Domain, Dr. Kamdar was a Kauffman Fellow with MPM Capital, as well as a research director at Novartis International AG. Dr. Kamdar serves on the board of Epic Sciences, Inc., Neothetics, Inc., Omniome, Inc., ROX Medical, Inc., Sera Prognostics, Inc., Syndax Pharmaceuticals, Inc. and Tragara Pharmaceuticals, Inc. Dr. Kamdar also previously served on the board of directors of Ariosa Diagnostics, Inc., a molecular diagnostics company, from 2010 until it was sold to Roche in January 2015. Ms. Kamdar serves as an advisory board member of Scripps Medicine and of Evolvence India Life Sciences Fund. She is also a board member of San Diego's CONNECT Foundation. Dr. Kamdar holds a B.A. from Northwestern University and a Ph.D. from Emory University. Our board of directors believes that Dr. Kamdar's extensive experience advising medical device companies qualifies her to serve on our board of directors.

Raymond Dittamore has served as a member of our board of directors since March 2016. Mr. Dittamore retired in June 2001 as a partner of Ernst & Young LLP, an international public accounting firm, after 35 years of service. Mr. Dittamore currently serves on the board of directors of QUALCOMM Incorporated, a semiconductor and telecommunications equipment company. Mr. Dittamore previously served on the boards of directors of Life Technologies Corporation, Gen-Probe Incorporation and Digirad Corporation. Mr. Dittamore holds a B.S. degree in accounting from San Diego State University. Our board of directors believes that Mr. Dittamore's extensive auditing and accounting experience as well as his industry knowledge qualifies him to serve on our board of directors.

Douglas Fisher has served as a member of our board since May 2012. Dr. Fisher is currently an Executive in Residence at InterWest Partners LLC, a venture capital firm, where he has worked since March 2009. Dr. Fisher also serves as the Chief Business Officer at Sera Prognostics, Inc., where he has worked since January 2015. Prior to joining InterWest, Dr. Fisher served as Vice President of New Leaf Venture Partners LLC, a private equity and venture capital firm, from January 2006 to March 2009. Prior to joining New Leaf, Dr. Fisher was a project leader with The Boston Consulting Group, Inc., a global management consulting firm, from November 2003 to February 2006. Dr. Fisher currently serves on the board of of Gynesonics, Inc., Indi Molecular, Inc. and QuatRx Pharmaceuticals Company and

previously served on the board of Cardiac Dimensions, PMV Pharmaceuticals, Inc., and Sera Prognostics, Inc. Dr. Fisher holds an A.B. and a B.S. from Stanford University, an M.D. from the University of Pennsylvania School of Medicine and an M.B.A. from The Wharton School of the University of Pennsylvania. Our board of directors believes that Dr. Fisher's extensive experience in the medical device industry qualifies him to serve on our board of directors.

Les Howe has served as a member of our board of directors since January 2016. Mr. Howe served as the Chief Executive Officer of Consumer Networks LLC, an internet marketing and promotions company, from December 2001 to May 2007. From July 1967 to September 1997, Mr. Howe held several positions at KPMG Peat Marwick LLP, an international auditing and accounting firm, and served as area managing partner/managing partner of their Los Angeles office from May 1994 to September 1997. Mr. Howe currently serves as the lead director of the board of directors of NuVasive, Inc., and has previously served on the board of directors of P.F. Chang's China Bistro, Inc., dj Orthopedics, Inc. and Jamba, Inc. Mr. Howe holds a B.S. and B.A. from the University of Arkansas. Our board of directors believes that Mr. Howe's extensive auditing and accounting experience qualifies him to serve on our board of directors.

Sharon Stevenson, DVM Ph.D. has served as a member of our board since January 2008. Dr. Stevenson is currently a Co-Founder and Managing Director of Okapi Venture Capital, a venture capital company, where she has worked since 2005. Prior to founding Okapi, Dr. Stevenson was the Senior Vice President of Technology and Planning for SkinMedica, Inc. (acquired by Allergan, Inc.) from 2003 to 2004. Prior to SkinMedica, Dr. Stevenson was a Principal with Domain Associates, LLC from 2000 to 2003. While at Domain, Dr. Stevenson also served as President and Chief Financial Officer of Volcano Corporation. Dr. Stevenson currently serves on the board of WiserCare, Inc., BioTrace Medical, Inc. and Focal Therapeutics, Inc., and has previously served on the board of directors of Helixis, Inc. (acquired by Illumina), OrthAlign, Inc. and PathCentral, Inc. Dr. Stevenson holds a Master of Science in Veterinary Pathology and Doctor of Veterinary Medicine from The Ohio State University, an M.B.A from the UCLA Anderson Graduate School of Management and a Ph.D. in Comparative Pathology from the University of California, Davis. Our board of directors believes that Dr. Stevenson's extensive industry experience and experience advising medical aesthetic companies qualifies her to serve on our board of directors.

ELECTION OF OFFICERS

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

BOARD OF DIRECTORS

Our current certificate of incorporation and voting agreement among certain investors provide that our board shall consist of seven directors, of which one director shall be elected by holders of our common stock, two directors shall be elected by holders of our preferred stock and all other directors shall be elected by the holders of our common stock and of every other class or series of voting stock (including all convertible preferred stock) voting together as a single class on an as-converted to common stock basis. Our board of directors currently consists of six members. Mr. Fisher and Dr. Kamdar are the designees of our preferred stock, Mr. Rasdal is the designee of our common stock and Dr. Stevenson, Mr. Howe and Mr. Dittamore are designees of our common stock and preferred stock voting together, with the one remaining designee of our common stock and preferred stock voting together remaining vacant.

The voting agreement and the provisions of our certificate of incorporation by which Drs. Fisher, Kamdar and Stevenson and Messrs. Rasdal, Howe and Dittamore were elected will terminate in connection with our initial public offering and there will be no contractual obligations regarding the election of our directors.

Each of our current directors will continue to serve until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

CLASSIFIED BOARD OF DIRECTORS

Our restated certificate of incorporation and restated bylaws that will be in effect immediately prior to the closing of this offering provide for a classified board of directors consisting of three classes of directors, each serving staggered three-year terms. As a result, one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows.

- the Class I directors will be Dr. Fisher and Dr. Stevenson, and their terms will expire at the first annual meeting of stockholders following this offering;
- the Class II directors will be Mr. Dittamore and Mr. Howe, and their terms will expire at the second annual meeting of stockholders following this offering; and
- the Class III directors will be Dr. Kamdar and Mr. Rasdal, and their terms will expire at the third annual meeting of stockholders following this offering.

Each director's term continues until the election and qualification of his or her successor, or his or her earlier death, resignation or removal. Our restated certificate of incorporation and restated bylaws that will be in effect immediately prior to the closing of this offering will authorize only our board of directors to fill vacancies on our board of directors. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The classification of our board of directors may have the effect of delaying or preventing a change of our management or a change in control of our company. Our directors will only be able to be removed for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock. See "Description of capital stock—Anti-takeover provisions—Restated certificate of incorporation and restated bylaws provisions."

DIRECTOR INDEPENDENCE

In connection with this offering, we have applied to list our common stock on The NASDAQ Global Market, or NASDAQ. Under NASDAQ rules, independent directors must comprise a majority of a listed company's board of directors within a specified period of the closing of this offering. In addition, NASDAQ rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Under NASDAQ rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not,

other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors determined that Drs. Fisher, Kamdar and Stevenson and Messrs. Dittamore and Howe, representing five of our six directors, are "independent directors" as defined under the applicable rules and regulations of the Securities and Exchange Commission, or the SEC, and the listing requirements and rules of NASDAQ. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain relationships and related-party transactions."

COMMITTEES OF THE BOARD OF DIRECTORS

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will have the composition and responsibilities described below as of the closing of our initial public offering. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee will operate under a charter approved by our board of directors. Following this offering, copies of each committee's charter will be posted on the investor relations section of our website at 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.

Audit committee

Our audit committee is comprised of Messrs. Howe and Dittamore and Ms. Stevenson. Mr. Howe is the chairperson of our audit committee. The composition of our audit committee meets the requirements for independence under the current NASDAQ listing standards and SEC rules and regulations. Each member of our audit committee meets the requirements for financial literacy under the applicable rules and regulations of the SEC and NASDAQ. In addition, our board of directors has determined that Mr. Howe is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act of 1933, as amended, or the Securities Act. This designation does not impose any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is responsible for, among other things:

- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements;
- our compliance with legal and regulatory requirements;
- reviewing and approving related-person transactions;
- selecting and hiring our independent registered public accounting firm;
- the qualifications, independence and performance of our independent auditors; and
- the preparation of the audit committee report to be included in our annual proxy statement.

Compensation committee

Our compensation committee is comprised of Mr. Dittamore and Ms. Kamdar. Mr. Dittamore is the chairperson of our compensation committee. The composition of our compensation committee meets the requirements for independence under the current NASDAQ listing standards and SEC rules and regulations. Each member of this committee is (i) an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and (ii) a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs;
- evaluating and recommending non-employee director compensation arrangements for determination by our board of directors;
- administering our cash-based and equity-based compensation plans; and
- overseeing our compliance with regulatory requirements associated with the compensation of directors, officers and employees.

Nominating and corporate governance committee

Our nominating and corporate governance committee is comprised of Messrs. Howe and Fisher and Ms. Kamdar. Ms. Kamdar is the chairperson of our nominating and corporate governance committee. The composition of our nominating and corporate governance committee meets the requirements for independence under the current NASDAQ listing standards and SEC rules and regulations. Our nominating and corporate governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on other corporate governance matters.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

None of the members of our compensation committee has at any time been one of our officers or employees, and none of our executive officers has served as a member of the board of directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our board of directors or compensation committee during the year ended December 31, 2015.

CODE OF BUSINESS CONDUCT AND ETHICS

Our board of directors adopted a code of business conduct and ethics that will become effective upon the closing of this offering that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our code of conduct will be posted on the investor relations section of our website at www.obalon.com. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. We intend to disclose future amendments to certain provisions of our code of conduct, or waivers of these provisions, on our website or in public filings to the extent required by the applicable rules and exchange requirements.

LIMITATIONS ON LIABILITY AND INDEMNIFICATION MATTERS

Our restated certificate of incorporation that will become effective immediately prior to the closing of this offering contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our restated certificate of incorporation and our restated bylaws that will become effective immediately prior to the closing of this offering require us to indemnify our directors and officers to the maximum extent not prohibited by the DGCL and allow us to indemnify other employees and agents as set forth in the DGCL. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors, officers and certain of our key employees, in addition to the indemnification provided for in our restated certificate of incorporation and restated bylaws. These agreements, among other things, require us to indemnify our directors, officers and key employees for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to us or any of our subsidiaries or any other company or enterprise to which these individuals provide services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted.

We believe that provisions of our restated certificate of incorporation, bylaws and indemnification agreements are necessary to attract and retain qualified directors, officers and key employees. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our restated certificate of incorporation and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

NON-EMPLOYEE DIRECTOR COMPENSATION

We did not pay any fees to, make any equity awards or non-equity awards to or pay any other compensation to the non-employee members of our board of directors in the year ended December 31, 2015. Additionally, none of our non-employee directors held any outstanding equity awards as of December 31, 2015. Mr. Rasdal, our Chief Executive Officer, received no compensation for his service as a director in the year ended December 31, 2015.

In connection with their appointments to our board of directors, in January and March 2016, we granted to each of Mr. Howe and Mr. Dittamore, respectively, an option to purchase 25,862 shares of common stock with an exercise price of $0.93 per share. These stock options will vest with respect to one quarter of the underlying shares on the first anniversary of their respective appointment dates, with the remaining shares vesting in equal monthly installments over the following 36 months, subject to acceleration upon a "change of control" of our company, as defined in the applicable award agreement. Each of the stock options may be exercised early at the option of the holder.

In August 2016, our board of directors approved non-employee director compensation that will provide each of our non-employee directors with an annual retainer of $35,000. Additionally, the chairperson of our board of directors will receive an additional annual payment of $25,000; the chairpersons of our audit, compensation and nominating and corporate governance committees will receive an additional annual payment of $17,500, $12,500 and $7,500, respectively; and the other members of our audit, compensation and nominating and corporate governance committees will receive an additional annual payment of $7,500, $5,000 and $5,000, respectively.

Each of our non-employee directors will also receive an annual stock option grant to purchase a number of shares of common stock with a value of $100,000 (determined using the Black-Scholes option value based on the 30-day trading average stock price), which stock option will vest in full on the one-year anniversary of the grant date, subject to the director's continued service. Additionally, new non-employee directors will receive a stock option to purchase a number of shares of common stock with a value of $300,000 (determined using the Black-Scholes option value based on the 30-day trading average stock price), which stock option will vest in equal monthly installments over three years, subject to the director's continued service.

Executive compensation

The following tables and accompanying narrative disclosure set forth information about the compensation provided to certain of our executive officers during the year ended December 31, 2015. These executive officers, who include our principal executive officer and the two most highly-compensated executive officers (other than our principal executive officer) who were serving as executive officers as of December 31, 2015, the end of our last completed fiscal year, were:

- Andrew Rasdal, President, Chief Executive Officer and Director;
- Mark Brister, Vice President of Research and Development; and
- Amy VandenBerg, Vice President of Regulatory and Clinical Affairs.

We refer to these individuals in this section as our "Named Executive Officers."

SUMMARY COMPENSATION TABLE

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our Named Executive Officers for services rendered during the year ended December 31, 2015.

Name and principal position	Salary	Option awards(1)	Non-equity incentive plan awards(2)	Total
Andrew Rasdal President and Chief Executive Officer	$400,000	$98,794	$100,000	$598,794
Mark Brister Vice President of Research and Development	$275,000	$28,147	$68,750	$371,897
Amy VandenBerg Vice President of Regulatory and Clinical Affairs	$260,000	$22,890	$65,000	$347,890

(1) The amounts shown represent the aggregate grant date fair value of stock options granted to each Named Executive Officer, as computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718. For a discussion of valuation assumptions used in the calculations, see Notes 2 and 7 to our audited consolidated financial statements included elsewhere in this prospectus. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by our Named Executive Officers from the options.

(2) For additional information regarding the non-equity incentive plan compensation, see "—Non-equity incentive plan awards."

Non-equity incentive plan awards

Annual bonuses for our executive officers are based on the achievement of corporate performance objectives. In 2015, these objectives included the completion of certain clinical development milestones related to our U.S. pivotal trial, improvements in product metrics as measured by specific reductions in failure and complaint rates, as well as the achievement of certain operational and financial targets. In January 2016, based on the achievement of these corporate performance objectives as of December 31, 2015, our board of directors determined to award bonuses equal to 25% of each executive officer's base salary. For 2015, each of Mr. Rasdal, Mr. Brister and Ms. VandenBerg were awarded the bonuses

reflected in the table above, which represented 25% of each individual's 2015 base salary of $400,000, $275,000 and $260,000, respectively.

Equity awards

In February 2015, our board of directors granted to each of Mr. Rasdal, Mr. Brister and Ms. VandenBerg options to purchase 228,674, 65,151 and 52,983 shares of common stock, respectively, each with an exercise price of $0.76 per share. One quarter of the shares underlying each of the options vested on January 1, 2016, with the remaining shares vesting in equal monthly installments over the following 36 months, subject to the respective individual's continued status as a service provider as of each vesting date. Each of the stock options may be exercised early at the option of the holder.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END TABLE

The following table presents, for each of the Named Executive Officers, information regarding outstanding stock options held as of December 31, 2015. All stock options are early exercisable for shares of our restricted common stock. As of December 31, 2015, no options have been early exercised.

	Option Awards					
Name	Grant date	Vesting commencement date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Andrew Rasdal	1/27/2010	12/24/2009	26,248(1)	—	$0.87	1/27/2020
	1/26/2011	9/8/2010	37,212(1)	—	$1.31	1/26/2021
	11/16/2011	11/16/2011	63,217(1)	—	$1.31	11/16/2021
	8/14/2012	6/14/2012	229,884(2)(3)	—	$1.83	8/14/2022
	2/12/2015	1/1/2015	228,674(2)(3)	—	$0.76	2/12/2025
Mark Brister	7/7/2008	6/16/2008	27,758(1)	—	$1.74	7/17/2018
	2/3/2009	2/3/2009	6,896(1)	—	$0.87	2/3/2019
	1/27/2010	12/24/2009	9,365(1)	—	$0.87	1/27/2020
	1/26/2011	9/8/2010	13,277(1)	—	$1.31	1/26/2021
	11/16/2011	11/16/2011	14,367(1)	—	$1.31	11/16/2021
	8/14/2012	6/14/2012	62,643(2)(3)	—	$1.83	8/14/2022
	2/12/2015	1/1/2015	65,151(2)(3)	—	$0.76	2/12/2025
Amy Vandenberg	12/15/2008	12/15/2008	4,022(1)	—	$0.87	12/15/2018
	1/27/2010	12/24/2009	1,087(1)	—	$0.87	1/27/2020
	1/26/2011	9/8/2010	1,541(1)	—	$1.31	1/26/2021
	7/27/2011	7/13/2011	9,770(1)	—	$1.31	7/27/2021
	4/10/2012	2/13/2012	10,448(2)(4)	—	$1.31	4/10/2022
	8/14/2012	6/14/2012	33,907(2)(4)	—	$1.83	8/14/2022
	12/19/2014	11/17/2014	12,214(2)(4)	—	$0.76	12/19/2024
	2/12/2015	1/1/2015	52,983(2)(4)	—	$0.76	2/12/2025

(1) Option is fully vested as of December 31, 2015.

(2) One-quarter of the shares underlying such option will vest on the first anniversary of the option vesting commencement date, with the remaining shares vesting in equal monthly installments for the following 36 months.

(footnotes continued on following page)

(3) 100% of all unvested shares subject to the option will vest and become exercisable in the event that we engage in a change of control transaction (as defined in the applicable award agreement).
(4) In the event that the holder is terminated by us without cause or resigns for good reason (each, as defined in the applicable award agreement), at any time during the period beginning on the closing of an acquisition (as defined in the applicable award agreement), and ending on the first anniversary of such closing, then 100% of any unvested shares subject to the stock options will automatically vest, subject to such holder executing and not rescinding a general release of claims.

EMPLOYMENT AGREEMENTS

We have entered into offer letters with certain senior management personnel, including our Named Executive Officers. Each of these offer letters provides for at-will employment and includes each officer's base salary, a discretionary annual incentive bonus opportunity and standard employee benefit plan participation.

Additionally, prior to the closing of this offering, we will enter into new retention agreements with each of the Named Executive Officers that will provide for severance benefits upon termination of employment or a change of control of our company. The severance benefits provided in these retention agreements will supersede any severance benefits provided in the Named Executive Officers' offer letters.

Chief executive officer severance benefits

The retention agreement that we will enter into with Mr. Rasdal will provide for the following benefits upon a qualifying termination, which means a termination by us without cause or a termination by the executive for good reason, outside of a change in control in exchange for a customary release of claims: (i) a lump sum severance payment of 12 months of base salary; (ii) 100% acceleration of any then-unvested equity awards, including awards that would vest only upon satisfaction of performance criteria; and (iii) payment of premiums for continued medical benefits (or equivalent cash payment if applicable law so requires) for up to 12 months. If Mr. Rasdal is subject to a qualifying termination within the three months preceding a change in control (but after a legally binding and definitive agreement for a potential change of control has been executed) or within the 12 months following a change in control, the retention agreement provides the following benefits in exchange for a customary release of claims: (i) a lump sum severance payment of 12 months of base salary, (ii) a lump sum payment equal to the pro rata portion of Mr. Rasdal's then-current target bonus opportunity, (iii) 100% acceleration of any then-unvested equity awards that were granted after this offering, and (iv) payment of premiums for continued medical benefits (or equivalent cash payment if applicable law so requires) for up to 12 months. Further, if a successor or acquiring entity does not assume, convert, replace or substitute Mr. Rasdal's equity awards in a change of control, the vesting of those unvested awards will accelerate in full. Additionally, if Mr. Rasdal ceases to provide services to us due to his death or disability and such separation occurs within 12 months following a change in control or within three months preceding a change in control if the separation occurs after a potential change in control, Mr. Rasdal's then-outstanding and unvested equity awards, including awards that would otherwise vest only upon satisfaction of performance criteria, will accelerate and become vested and exercisable as to 100% of the then-unvested shares. Mr. Rasdal's retention agreement will be in effect for three years, with automatic three-year renewals unless notice is given by us to Mr. Rasdal three months prior to expiration.

As used in Mr. Rasdal's retention agreement, "cause" means: (i) conviction for, or guilty plea to, a felony involving moral turpitude; (ii) an uncured willful refusal to comply with our lawful and reasonable instructions, or to otherwise perform duties as we lawfully and reasonably determine; (iii) any willful act of dishonesty intended to result in material gain or personal enrichment at the expense of us or any of

our customers, partners, affiliates or employees; or (iv) any willful act of gross misconduct that is injurious to us. "Change in control" has the same meaning as "corporate transaction" under our 2016 Equity Incentive Plan, as further described below. "Disability" means total and permanent disability as defined by our long-term disability benefit plan. "Good reason" means, without consent, and subject to certain exceptions, (i) a reduction in then-current base salary (except for a reduction that is part of a proportional reduction of the base salaries of all executives), bonus opportunity or commissions opportunity; (ii) our offices being moved such that the usual commuting distance is increased by more than 10 miles; (iii) a material and adverse change to duties or responsibilities; (iv) a change to title and/or role after which Mr. Rasdal is not both the Chief Executive Officer of the top-level acquiring entity whose stock is publicly traded and a voting member of its board of directors; (v) Mr. Rasdal is not, so long as he is Chief Executive Officer, a voting member of our board of directors; or (vi) we provide notice that the retention agreement will not be renewed.

Other executive officer severance benefits

The retention agreements that we will enter into with Mr. Brister and Ms. VandenBerg will provide for the following benefits upon a qualifying termination, which means a termination by us without cause or a termination by the executive for good reason, outside of a change in control in exchange for a customary release of claims: (i) a lump sum severance payment of six months of base salary and (ii) payment of premiums for continued medical benefits (or equivalent cash payment if applicable law so requires) for up to six months. If either of Mr. Brister or Ms. VandenBerg is subject to a qualifying termination within the three months preceding a change in control (but after a legally binding and definitive agreement for a potential change of control has been executed) or within the 12 months following a change in control, the retention agreements provide the following benefits to such individual in exchange for a customary release of claims: (i) a lump sum severance payment of 12 months of base salary, (ii) a lump sum payment equal to the pro rata portion such individual's then-current target bonus opportunity, (iii) 100% acceleration of any then-unvested equity awards that were granted after this offering, and (iv) payment of premiums for continued medical benefits (or equivalent cash payment if applicable law so requires) for up to 12 months. Further, if a successor or acquiring entity does not assume, convert, replace or substitute the executive's equity awards in a change of control, the vesting of those unvested awards will accelerate in full. Each retention agreement is in effect for three years, with automatic three-year renewals unless notice is given by us to the Named Executive Officer three months prior to expiration.

As used in the retention agreements, "cause" means: (i) conviction for, or guilty plea to, a felony involving moral turpitude; (ii) an uncured willful refusal to comply with our lawful and reasonable instructions, or to otherwise perform duties as we lawfully and reasonably determine; (iii) any willful act of dishonesty intended to result in material gain or personal enrichment at the expense of us or any of our customers, partners, affiliates or employees; or (iv) any willful act of gross misconduct that is injurious to us. "Change in control" has the same meaning as "corporate transaction" under our 2016 Equity Incentive Plan, as further described below. "Good reason" means, without consent, and subject to certain exceptions, (i) a reduction in then-current base salary (except for a reduction that is part of a proportional reduction of the base salaries of all executives), bonus opportunity or commissions opportunity; (ii) our offices being moved such that the usual commuting distance is increased by more than 10 miles; and (iii) a material and adverse change to title, duties or responsibilities.

BONUS PLAN

Our board of directors adopted a Bonus Plan, effective on the date immediately prior to the effective date of the registration statement of which this prospectus is a part. The Bonus Plan provides for the potential

payment of cash bonuses to selected employees, including our Named Executive Officers. Each year, our compensation committee will establish a bonus pool from which awards will be paid and will, in its sole discretion, determine the performance goals applicable to any award, which may be selected from the list of performance factors identified in our 2016 Equity Incentive Plan. The performance goals and the time period over which such goals are measured may differ from participant to participant and from award to award. The performance goals may be based on GAAP or non-GAAP results and any actual results may be adjusted by the compensation committee for one-time items, unbudgeted or unexpected items, acquisition-related activities or changes in applicable accounting rules when determining whether the performance goals have been met.

Bonuses awarded under the Bonus Plan will be paid in cash as soon as practicable after we announce our financial results for the relevant fiscal year, which generally occurs in the first quarter of the succeeding year. Bonuses, if any, will be paid before March 15 of such succeeding calendar year.

EMPLOYEE BENEFIT AND STOCK COMPENSATION PLANS

2008 equity incentive plan

Our board of directors adopted our 2008 Equity Incentive Plan, or the 2008 Plan, in February 2008. The 2008 Plan provides for the grant of incentive stock options, which qualify for favorable tax treatment to their recipients under Section 422 of the Code, and nonstatutory stock options, as well as for the issuance of shares of restricted stock. We may grant incentive stock options only to our employees, including officers and directors who are also employees. We may grant nonstatutory stock options to our employees, officers, directors and consultants. We have only granted stock options under our 2008 Plan.

Our 2008 Plan is administered by our board of directors. Our board of directors has the authority to construe and interpret our 2008 Plan, grant awards, determine the terms of such awards and make all other determinations necessary or advisable for the administration of the 2008 Plan.

The exercise price of each stock option must be at least equal to the fair market value of our common stock on the date of grant. The exercise price of incentive stock options granted to 10% stockholders must be at least equal to 110% of the fair market value of our common stock on the date of grant. The maximum permitted term of options granted under our 2008 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to 10% stockholders is five years from the date of grant.

Options granted under our 2008 Plan to date generally vest over a four-year period subject to the optionee's continued service through certain vesting dates and may not be transferred in any manner other than by will or by the laws of descent and distribution or as determined by our board of directors. Unless otherwise permitted by our board of directors, stock options may be exercised during the lifetime of the optionee only by the optionee or the optionee's guardian or legal representative. The 2008 Plan provides that options generally may be exercised for a period of three months after the termination of the optionee's service to us for any reason other than due to death or disability, and for a period of six months in the case of death or disability, or such longer period as our board of directors may provide. Options granted under our 2008 Plan to date generally may be may be exercised for a period of ninety days after the termination of the optionee's service to us for any reason other than due to death or disability, and for a period of one year in the case of death or disability.

In the event of a merger or change in control (as defined in the 2008 Plan), the 2008 Plan provides that awards may be assumed or substituted by the successor or acquiring entity. If any surviving or acquiring

corporation fails to assume or substitute such awards, awards held by participants whose continuous service has not terminated will accelerate vesting in full prior to the transaction. All awards will terminate at or prior to the date of the transaction. A stock option shall be considered assumed if, following the transaction, the stock option confers the right to receive a payment, if any, equal to the consideration payable to a holder of common stock for each share underlying the stock option less the exercise price otherwise payable in connection with the stock option.

In the event there is a specified type of change in our capital structure without our receipt of consideration, such as a stock split, our board of directors may (in its sole discretion) make appropriate adjustments to the number of shares reserved under our 2008 Plan, and the number of shares and exercise price, if applicable, of all outstanding stock options under our 2008 Plan.

As of June 30, 2016, we had reserved 2,988,770 shares of our common stock for issuance under our 2008 Plan, which was reduced to 2,380,074 shares on July 17, 2016. As of June 30, 2016, options to purchase 1,767,690 of these shares were outstanding and 1,056,415 of these shares were available for grant (which was reduced to 447,719 shares on July 17, 2016). We will cease issuing awards under the 2008 Plan upon the effective date of the 2016 Equity Incentive Plan, or the 2016 Plan. The 2016 Plan will become effective on the date immediately prior to the effective date of the registration statement of which this prospectus is a part. As a result, we will not grant any additional options under the 2008 Plan following that date, and the 2008 Plan will terminate at that time. However, any outstanding options granted under the 2008 Plan will remain outstanding, subject to the terms of the 2008 Plan and stock option agreements, until such outstanding options are exercised or until they terminate or expire by their terms.

2016 equity incentive plan

Our board of directors adopted the 2016 Plan, which will become effective on the date immediately prior to the effective date of the registration statement of which this prospectus is a part and serve as the successor to the 2008 Plan. We have reserved 2,200,000 shares of our common stock to be issued under the 2016 Plan. The number of shares reserved for issuance under the 2016 Plan will increase automatically on January 1 of each of our calendar years beginning 2017 and continuing through 2026 by the number of shares equal to 4% of the total outstanding shares of our common stock and common stock equivalents as of the immediately preceding December 31. However, our board of directors may reduce the amount of the increase in any particular year. In addition, the following shares of our common stock will be available for grant and issuance under the 2016 Plan:

- shares subject to options or stock appreciation rights, or SARs, granted under the 2016 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;
- shares subject to awards granted under the 2016 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under the 2016 Plan that otherwise terminate without shares being issued;
- shares surrendered, cancelled, or exchanged for cash or a different award (or combination thereof);
- shares subject to awards under the 2016 Plan that are used to pay the exercise price of an award or withheld to satisfy the tax withholding obligations related to any award;
- shares reserved but not issued or subject to outstanding awards under the 2008 Plan on the effective date of the 2016 Plan;

- shares issuable upon the exercise of options or subject to other awards under the 2008 Plan prior to the date of this prospectus that cease to be subject to such options or other awards by forfeiture or otherwise after the effective date of the 2016 Plan;
- shares issued under the 2008 Plan that are repurchased by us at the original issue price or are forfeited after the effective date of the 2016 Plan; and
- shares subject to awards under the 2008 Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

The 2016 Plan authorizes the award of stock options, restricted stock, or RSAs, SARs, restricted stock units, or RSUs, performance awards and stock bonuses. No person will be eligible to receive more than 350,000 shares in any calendar year under the 2016 Plan other than a new employee of ours, who will be eligible to receive no more than 1,000,000 shares under the plan in the calendar year in which the employee commences employment. No participant will be eligible to receive more than $10,000,000 in performance awards in any calendar year. No more than 4,400,000 shares will be issued pursuant to the exercise of incentive stock options. The aggregate number of shares of our common stock that may be subject to awards granted to any one non-employee director pursuant to the 2016 Plan in any calendar year shall not exceed 220,000.

The 2016 Plan will be administered by our compensation committee, all of the members of which are outside directors as defined under applicable federal tax laws, or by our board of directors acting in place of our compensation committee. The compensation committee will have the authority to construe and interpret the 2016 Plan, grant awards and make all other determinations necessary or advisable for the administration of the plan.

The 2016 Plan will provide for the grant of awards to our employees, directors, consultants, independent contractors and advisors, provided the consultants, independent contractors, non-employee directors and advisors render services not in connection with the offer and sale of securities in a capital-raising transaction. The exercise price of stock options must be at least equal to the fair market value of our common stock on the date of grant. The compensation committee has the authority to reprice any outstanding stock option or SAR (by reducing the exercise price of any outstanding option or SAR, canceling an option or SAR in exchange for cash or another equity award) under the 2016 Plan without the approval of our stockholders.

Options may vest based on time or achievement of performance conditions. Our compensation committee may provide for options to be exercised only as they vest or to be immediately exercisable with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. The maximum term of options granted under the 2016 Plan is ten years.

An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may vest based on time or achievement of performance conditions. The price, if any, of an RSA will be determined by the compensation committee. Unless otherwise determined by the compensation committee at the time of award, vesting will cease on the date the holder no longer provides services to us and unvested shares will be forfeited to or repurchased by us.

SARs provide for a payment, or payments, in cash or shares of our common stock, to the holder based upon the difference between the fair market value of our common stock on the date of exercise and the stated exercise price at grant up to a maximum amount of cash or number of shares. SARs may vest based on time or achievement of performance conditions.

RSUs represent the right to receive shares of our common stock at a specified date in the future, subject to forfeiture of that right because of termination of employment or failure to achieve certain performance conditions. If an RSU has not been forfeited, then on the date specified in the RSU agreement, we will deliver to the holder of the RSU shares of our common stock (which may be subject to additional restrictions), cash or a combination of our common stock and cash.

Performance awards cover a number of shares of our common stock that may be settled upon achievement of the pre-established performance conditions as provided in the 2016 Plan in cash or by issuance of the underlying shares or other property (or any combination thereof). These awards are subject to forfeiture prior to settlement due to termination of employment or failure to achieve the performance conditions.

Stock bonuses may be granted as additional compensation for past or future service or performance, and therefore, no payment will be required for any shares awarded under a stock bonus. Unless otherwise determined by the compensation committee at the time of award, vesting will cease on the date the holder no longer provides services to us and unvested shares (if any) will be forfeited to us.

The 2016 Plan permits the grant of performance-based awards that may qualify as performance-based compensation that is not subject to the $1.0 million limitation on income tax deductibility imposed by Section 162(m) of the Code. Our compensation committee may structure awards so that the cash, stock or other property will be paid or issued only following the achievement of certain pre-established performance goals during a designated performance period.

Awards granted under the 2016 Plan may not be transferred in any manner other than by will or by the laws of descent and distribution or as determined by our compensation committee. Unless otherwise permitted by our compensation committee, stock options may be exercised during the lifetime of the optionee only by the optionee or the optionee's guardian or legal representative. Options granted under the 2016 Plan generally may be exercised for a period of three months after the termination of the optionee's service to us, for a period of 12 months in the case of death or disability, or such longer period as our compensation committee may provide. Options generally terminate immediately upon termination of employment for cause.

In the event there is a specified type of change in our capital structure without our receipt of consideration, such as a stock split, appropriate adjustments will be made to the number of shares reserved under the 2016 Plan, the maximum number of shares that can be granted in a calendar year and the number of shares and exercise price, if applicable, of all outstanding awards under the 2016 Plan.

If we are party to a merger or consolidation, sale of all or substantially all assets or similar change in control transaction, outstanding awards, including any vesting provisions, may be continued, assumed or substituted by the successor company. In the alternative, outstanding awards may be replaced at their full value with cash (or cash equivalents) or securities of the successor entity (or its parent). Outstanding awards may also be cancelled in exchange for no consideration and/or vesting may be accelerated in full or in part. Outstanding awards that are not converted, assumed, substituted or replaced will be exercisable for a period of time determined by the committee, and those awards will terminate upon expiration of such period to the extent not exercised. Awards held by non-employee directors will immediately vest as to all or any portion of the shares subject to the stock award and will become exercisable at such times and on such conditions as the compensation committee determines.

The 2016 Plan will terminate ten years from the effective date of the registration statement of which this prospectus is a part, unless it is terminated earlier by our board of directors. Our board of directors may

amend or terminate the 2016 Plan at any time. If our board of directors amends the 2016 Plan, it does not need to ask for stockholder approval of the amendment unless required by applicable law.

2016 employee stock purchase plan

Our board of directors adopted a 2016 Employee Stock Purchase Plan, or the 2016 ESPP, in order to enable eligible employees to purchase shares of our common stock at a discount following the date of this offering. Purchases will be accomplished through participation in discrete offering periods. The 2016 ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Code. We have reserved 180,000 shares of our 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 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. However, our board of directors or compensation committee may reduce the amount of the increase in any particular year. The aggregate number of shares issued over the term of the 2016 ESPP will not exceed 17,000,000 shares of our common stock.

Our compensation committee will administer the 2016 ESPP. Our employees generally are eligible to participate in the 2016 ESPP. Employees who are 5% stockholders, or would become 5% stockholders as a result of their participation in the 2016 ESPP, are ineligible to participate in the 2016 ESPP. We may impose additional restrictions on eligibility. Under the 2016 ESPP, eligible employees will be able to acquire shares of our common stock by accumulating funds through payroll deductions. Our eligible employees will be able to select a rate of payroll deduction between 1% and 15% of their eligible cash compensation. We will also have the right to amend or terminate the 2016 ESPP at any time. The 2016 ESPP will terminate on the tenth anniversary of the effective date of the registration statement of which this prospectus is a part, unless it is terminated earlier by our board of directors.

The 2016 ESPP is implemented through a series of offering periods with durations of not more than 27 months under which our employees who meet the eligibility requirements for participation in that offering period will automatically be granted a nontransferable option to purchase shares in that offering period. For subsequent offering periods, new participants will be required to enroll in a timely manner. Once an employee is enrolled, participation will be automatic in subsequent offering periods. Except for the first offering period, each offering period will run for six months. The first offering period began upon the effective date of this offering and will end on May 1, 2017, or another date selected by our compensation committee, but no more than 27 months after the commencement of the initial offering period. Thereafter, a six-month offering period will commence on each May 1 and November 1, or another date selected by our compensation committee. An employee's participation automatically ends upon termination of employment for any reason.

No participant will have the right to purchase shares of our common stock in an amount, when aggregated with purchase rights under all our employee stock purchase plans that are also in effect in the same calendar year, that have a fair market value of more than $25,000, determined as of the first day of the applicable purchase period, for each calendar year in which that right is outstanding. In addition, no participant will be permitted to purchase more than 5,000 shares during any one purchase period or a lesser amount determined by our compensation committee. The purchase price for shares of our common stock purchased under the 2016 ESPP will be 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period and (ii) the last trading day of each purchase period in the applicable offering period. The fair market value of our common stock for purposes of our first offering period under the 2016 ESPP will be the price at which shares are first sold to the public under this offering.

If we experience a change of control transaction, any offering period that commenced prior to the closing of the proposed change of control transaction will be shortened and terminated on a new purchase date. The new purchase date will occur prior to the closing of the proposed change of control transaction and the 2016 ESPP will then terminate on the closing of the proposed change of control.

401(k) plan

We sponsor a retirement plan intended to qualify for favorable tax treatment under Section 401(a) of the Code, containing a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. U.S. employees who have attained at least 21 years of age are generally eligible to participate in the plan the first day of the month that coincides with or next follows the day you become an eligible employee. The plan is subject to certain eligibility requirements. Participants may make pre-tax contributions to the plan from their eligible earnings up to the statutorily prescribed annual limit on pre-tax contributions under the Code. Participants who are 50 years of age or older may contribute additional amounts based on the statutory limits for catch-up contributions. Pre-tax contributions by participants and the income earned on those contributions are generally not taxable to participants until withdrawn. Plan participants may contribute Roth Contributions which are withheld from the paycheck with "after tax" contributions and are generally tax free when they are withdrawn from the plan. Participant contributions are held in trust as required by law. No minimum benefit is provided under the plan. An employee's interest in his or her pre-tax deferrals is 100% vested when contributed. Although the plan provides for a discretionary employer matching contribution, to date we have not made such a contribution on behalf of employees. The plan permits all eligible plan participants to contribute between 1% and 100% of eligible compensation, on a pre-tax basis, into their accounts.

Certain relationships and related-party transactions

The following is a summary of transactions since January 1, 2013 to which we have been or will be a party in which the amount involved exceeded or will exceed $120,000 and in which any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing a household with, any of these individuals, had or will have a direct or indirect material interest, other than compensation arrangements that are described under the section of this prospectus captioned "Management—Non-employee director compensation" and "Executive compensation."

EQUITY FINANCINGS

Series D convertible preferred stock financing

In three closings in August 2014, November 2014 and December 2014, we issued and sold an aggregate of 2,732,552 shares of our Series D convertible preferred stock at a purchase price of $7.5351 per share for an aggregate purchase price of approximately $20.6 million. Each share of our Series D convertible preferred stock will convert automatically into one share of our common stock immediately prior to the closing of this offering.

The purchasers of our Series D convertible preferred stock are entitled to specified registration rights. For additional information, see "Description of capital stock—Registration rights." The following table summarizes the Series D convertible preferred stock purchased by our directors, executive officers and beneficial holders of more than 5% of our capital stock. The terms of these purchases were the same for all purchasers of our Series D convertible preferred stock.

Name of stockholder	Shares of Series D convertible preferred stock	Total purchase price
Bader Sultan & Bros. Co. W.L.L(1)	875,903	$6,599,999
Domain Partners VII, L.P.(2)	597,207	$4,500,001
InterWest Partners X, L.P.(3)	464,494	$3,500,001
Okapi Ventures II, L.P.(4)	119,441	$ 899,999

(1) Bader Sultan & Bros. Co. W.L.L. is the sole distributor of our products in the Middle East.
(2) Kim Kamdar, a member of our board of directors, is a member of One Palmer Square Associates VII, L.L.C., the general partner of Domain Partners VII, L.P.
(3) Douglas Fisher, a member of our board of directors, is an Executive in Residence at InterWest Partners LLC, an affiliate of InterWest Partners X, L.P.
(4) Sharon Stevenson, a member of our board of directors, is a managing director of Okapi Venture Partners II, LLC, which is the general partner of Okapi Ventures II, L.P.

Series E convertible preferred stock financing

In two closings in April 2016 and May 2016, we issued and sold an aggregate of 1,916,425 shares of our Series E convertible preferred stock at a purchase price of $8.2932 per share for an aggregate purchase price of approximately $15.8 million. Each share of our Series E convertible preferred stock will convert automatically into one share of our common stock immediately prior to the closing of this offering.

The purchasers of our Series E convertible preferred stock are entitled to specified registration rights. For additional information, see "Description of capital stock—Registration rights." The following table summarizes the Series E convertible preferred stock purchased by our directors, executive officers and beneficial holders of more than 5% of our capital stock. The terms of these purchases were the same for all purchasers of our Series E convertible preferred stock.

Name of stockholder	Shares of Series E convertible preferred stock	Total purchase price
Bader Sultan & Bros. Co. W.L.L(1)	154,585	$1,281,998
Domain Partners VII, L.P.(2)	482,326	$4,000,000
InterWest Partners X, L.P.(3)	373,803	$3,099,998
Entities affiliated with Okapi Ventures(4)	107,919	$ 894,997

(1) Bader Sultan & Bros. Co. W.L.L. is the sole distributor of our products in the Middle East.
(2) Kim Kamdar, a member of our board of directors, is a member of One Palmer Square Associates VII, L.L.C., the general partner of Domain Partners VII, L.P.
(3) Douglas Fisher, a member of our board of directors, is an Executive in Residence at InterWest Partners LLC, an affiliate of InterWest Partners X, L.P.
(4) Consists of 60,290 shares purchased by Okapi Ventures II, L.P. and 47,629 shares purchased by Okapi Ventures, L.P. Sharon Stevenson, a member of our board of directors, is a managing director of Okapi Venture Partners II, LLC and Okapi Venture Partners, LLC, which are the general partners of Okapi Ventures II, L.P. and Okapi Ventures, L.P., respectively.

TRANSACTIONS WITH BADER

In June 2013, we entered into a distribution agreement with Bader Sultan & Bros. Co. W.L.L., or Bader, a healthcare products distributor based in Sufat, Kuwait. Pursuant to the distribution agreement, we appointed Bader as the exclusive distributor of our products in the Middle East. Sales to Bader for the years ended December 31, 2013, 2014 and 2015 and the six months ended June 30, 2016 totaled $0.2 million, $1.9 million, $3.8 million and $1.8 million, respectively. The distribution agreement was entered into and the transactions under it are completed on an arm's length basis in the normal course of business.

In August 2014, Bader became a stockholder. For additional information, please see "—Series D convertible preferred stock financing" and "—Series E convertible preferred stock financing" As of June 30, 2016, Bader owned approximately 9.4% of our outstanding capital stock on an as-converted to common stock basis.

POTENTIAL INSIDER PARTICIPATION

Certain of our stockholders and their affiliates, some of which are affiliated with our directors, have indicated an interest in purchasing shares of common stock in this offering with an aggregate value of approximately $20.0 million at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering.

FOURTH AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT

We have entered into an investors' rights agreement with certain holders of our common stock and holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. These stockholders are entitled to rights with respect to the registration of their shares

following our initial public offering under the Securities Act. For a description of these registration rights, see "Description of capital stock—Registration rights."

INDEMNIFICATION AGREEMENTS

In connection with this offering, we intend to enter into new indemnification agreements with each of our directors and executive officers. The indemnification agreements, our restated certificate of incorporation and our restated bylaws will require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and officers. For more information regarding these agreements, see "Management—Limitations on liability and indemnification matters."

REVIEW, APPROVAL OR RATIFICATION OF TRANSACTIONS WITH RELATED PARTIES

In connection with this offering, we adopted a written related-person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family or affiliates of the foregoing persons, are not permitted to enter into a material related-person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. The policy provides that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate family members or affiliates, in which the amount involved exceeds $120,000 will be presented to our audit committee (or the committee composed solely of independent directors, if applicable) for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee (or the committee composed solely of independent directors, if applicable) will consider the relevant facts and circumstances available and deemed relevant to the audit committee (or the committee composed solely of independent directors, if applicable), including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Principal stockholders

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of our common stock at August 31, 2016, and as adjusted to reflect the shares of common stock to be issued and sold in this offering assuming no exercise of the underwriters' option to purchase additional shares, for:

- each of our directors;
- each of our Named Executive Officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who beneficially owned more than 5% of our outstanding common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Beneficial ownership prior to this offering is based on 11,707,687 shares of common stock outstanding as of August 31, 2016, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into 10,360,419 shares of common stock. Beneficial ownership after this offering is based on 16,719,904 shares of common stock outstanding, assuming (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 10,360,419 shares of common stock as described above, (ii) the issuance of 5,000,000 shares of common stock in this offering and (iii) 12,217 shares that we expect to issue upon the automatic net exercise of warrants immediately prior to the closing of this offering, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants or other rights held by that person or entity that are currently exercisable or that will become exercisable within 60 days of August 31, 2016. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Obalon Therapeutics, Inc., 5421 Avenida Encinas, Suite F, Carlsbad, California 92008.

The table below does not reflect any shares that may be purchased by our directors, executive officers or significant stockholders pursuant to the directed share program.

Certain of our stockholders and their affiliates, some of which are affiliated with our directors, have indicated an interest in purchasing shares of common stock in this offering with an aggregate value of approximately $20.0 million at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering. The information set forth below does not reflect any potential purchase of any shares in this offering by such parties.

Name of beneficial owner	Beneficial ownership prior to this offering		Beneficial ownership after this offering	
	Number	Percentage	Number	Percentage
5% or Greater Stockholders				
Entities affiliated with Domain Partners(1)	4,055,727	34.6%	4,055,727	24.2%
InterWest Partners X, L.P.(2)	2,453,338	21.0%	2,453,338	14.7%
Bader Sultan & Bros. Co. W.L.L.(3)	1,030,488	8.8%	1,030,488	6.2%
Entities affiliated with Okapi Venture Capital(4)	891,504	7.7%	891,504	5.4%
Named Executive Officers and Directors				
Andrew Rasdal(5)	828,911	6.9%	828,911	4.9%
Mark Brister(6)	240,834	2.0%	240,834	1.4%
Amy VandenBerg(7)	160,454	1.4%	160,454	1.0%
Ray Dittamore(8)	25,862	*	25,862	*
Douglas Fisher	—	—	—	—
Les Howe(8)	25,862	*	25,862	*
Kim Kamdar	—	—	—	—
Sharon Stevenson(4)	891,504	7.7%	891,504	5.4%
All executive officers and directors as a group (14 persons)(9)	2,751,001	21.6%	2,751,001	15.5%

* Represents beneficial ownership of less than one percent.

(1) Represents (a)(i) 3,985,971 shares of common stock held by Domain Partners VII, L.P., or Domain Partners, and (ii) 19,849 shares underlying warrants to purchase common stock held by Domain Partners, which are exercisable within 60 days of August 31, 2016 and (b)(i) 49,570 shares held by DP VII Associates, L.P., or DP Associates, and (ii) 338 shares underlying warrants to purchase common stock held by DP Associates, which are exercisable within 60 days of August 31, 2016. One Palmer Square Associates VII, L.L.C., or One Palmer Square, is the general partner of each of Domain Partners and DP Associates. James C. Blair, Brian H. Dovey, Jesse I. Treu, Nicole Vitullo and Brian K. Halak are the managing members of One Palmer Square, and share voting and investment power over the shares. The address of One Palmer Square is One Palmer Square, Suite 515, Princeton, New Jersey 08542.

(2) Represents shares of common stock held by InterWest Partners X, L.P., or IW10. InterWest Management Partners X, LLC, or IMP10, is the general partner of IW10. Philip T. Gianos, W. Stephen Holmes, Gilbert H. Kliman and Arnold L. Oronsky are the managing directors of IMP10, and Keval Desai and Khalad A. Nasr are venture members of IMP10, and all of these individuals share voting and investment power over the shares. The address of InterWest Partners is 2710 Sand Hill Road, Suite 200, Menlo Park, California 94025.

(3) Represents shares of common stock held by Bader Sultan & Bros. Co. W.L.L., or Bader, of which Anwar Sultan Al-Essa is a managing director and has voting and investment power over the shares. The address of Bader is P.O. Box 867, 13009 Kuwait.

(4) Represents (i)(a) 546,232 shares of common stock held by Okapi Ventures, L.P., or OV, and (b) 4,037 shares underlying warrants to purchase common stock held by OV that are exercisable within 60 days of August 31, 2016 and (ii) 341,235 shares held by Okapi Ventures II, L.P., or OVII. Okapi Venture Partners, LLC and Okapi Venture Partners II, LLC are the general partners of OV and OVII, respectively. Sharon Stevenson, a member of our board of directors, and B. Marc Averitt, are the managing directors of Okapi Venture Partners, LLC and Okapi Venture Partners II, LLC, and share voting and investment power over the shares. The address of Okapi Venture Capital is 1590 South Coast Highway, No. 10, Laguna Beach, California 92651.

(footnotes continued on following page)

(5) Represents (i) 353,369 shares of common stock held by Mr. Rasdal, (ii) 97,126 shares of common stock held by The Rasdal Family Trust dated December 10, 1996, of which Mr. Rasdal and his spouse serve as trustees, and (iii) 378,416 shares underlying options to purchase common stock held by Mr. Rasdal that are exercisable within 60 days of August 31, 2016, of which 259,915 shares are unvested but early exercisable.
(6) Represents (i) 160,460 shares of common stock and (ii) 80,374 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2016, of which 73,716 shares are unvested but early exercisable.
(7) Represents 160,454 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2016, of which 67,055 shares are unvested but early exercisable.
(8) Represents 25,862 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2016, all of which shares are unvested but early exercisable.
(9) Represents (i) 1,747,037 shares of common stock, (ii) 4,037 shares underlying warrants to purchase common stock that are exercisable within 60 days of August 31, 2016 and (iii) 999,927 shares underlying options to purchase common stock that are exercisable within 60 days of August 31, 2016, of which 905,357 shares are unvested but early exercisable. Such shares are held by our executive officers, who are Andrew Rasdal, William Plovanic, Mark Brister, Nooshin Hussainy, Steve Johnson, Lisa Metzner, Matthew Norwood, Amy VandenBerg and Donald Young, and our directors, who are Kim Kamdar, Ray Dittamore, Douglas Fisher, Les Howe and Sharon Stevenson.

Description of capital stock

The following is a summary of the rights of our common and preferred stock and some of the provisions of our restated certificate of incorporation and restated bylaws, which will become effective immediately prior to the closing of this offering, and of the Delaware General Corporation Law, or DGCL. Immediately prior to the closing of this offering, and upon the filing of our restated certificate of incorporation, our authorized capital stock will consist of 300,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.001 par value per share.

As of June 30, 2016, there were 580,835 shares of our common stock outstanding. Pursuant to the provisions of our current certificate of incorporation and the written consent of our stockholders, all of our outstanding convertible preferred stock will automatically convert into an aggregate of 10,360,419 shares of common stock effective immediately prior to the closing of this offering. Each series of our convertible preferred stock will convert to common stock at a ratio of 1:1, except for our Series A convertible preferred stock, which will convert at a ratio of 1:1.32784. Based on the number of shares of common stock outstanding as of June 30, 2016, and assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, as of June 30, 2016, there were 10,941,254 shares of our common stock issued and outstanding, held by approximately 42 stockholders of record, and no shares of our preferred stock outstanding.

COMMON STOCK

Voting rights

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

Dividend rights

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

No preemptive or similar rights

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

Right to receive liquidation distributions

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

PREFERRED STOCK

Pursuant to the provisions of our current certificate of incorporation, all of our outstanding convertible preferred stock will automatically convert into common stock immediately prior to the closing of this offering. As a result, each currently outstanding share of convertible preferred stock will be converted into common stock at a ratio of 1:1, except for the Series A convertible preferred stock, which will convert at a ratio of 1:1.32784.

Pursuant to our restated certificate of incorporation that will become effective immediately prior to the closing of this offering, our board of directors will be authorized, subject to limitations prescribed by Delaware law, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors will also be able to increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may be able to authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

STOCK OPTIONS

As of June 30, 2016, we had outstanding options to purchase an aggregate of 1,767,690 shares of our common stock, with a weighted-average exercise price of approximately $1.41 per share. Subsequent to June 30, 2016, we issued options to purchase an aggregate of 229,528 shares of our common stock, with an exercise price of $2.82 per share.

WARRANTS

As of June 30, 2016, we had outstanding (i) three warrants to purchase an aggregate of 24,224 shares of our Series C convertible preferred stock at an exercise price of $6.1918 per share, which expire in

February 2019, (ii) a warrant to purchase 8,693 shares of our Series C-1 convertible preferred stock at an exercise price of $10.36 per share, which expires in June 2023, and (iii) a warrant to purchase 27,869 shares of our Series D convertible preferred stock at an exercise price of $7.5351 per share, which expires in October 2024. Subsequent to June 30, 2016, we issued a warrant to purchase that number of shares of our Series E convertible preferred stock, at a purchase price of $8.2932 per share, equal to 3.0% of the total additional amount of debt drawn under our loan and security agreement with Pacific Western Bank (up to $5.0 million) divided by the purchase price, which will only be exercisable in the event that we borrow such additional amount and expires in March 2017. Such warrant is exercisable to purchase a maximum of 18,087 shares, depending on the amount of debt drawn. Each of these warrants has a cashless exercise provision under which the holder, in lieu of paying the exercise price in cash, can surrender the warrant and receive a net number of shares based on the fair market value of such stock at the time of exercise, after deducting the aggregate exercise price. Pursuant to their terms, upon the closing of this offering, each of these warrants will convert into a warrant to purchase the same number of shares of common stock at its original exercise price.

As of June 30, 2016, we also had outstanding two warrants to purchase an aggregate of 24,550 shares of our Series D convertible preferred stock at an exercise price of $7.5351 per share. Each of these warrants has a cashless exercise provision under which the holder, in lieu of payment of the exercise price in cash, can surrender the warrant and receive a net number of shares based on the fair market value of such stock at the time of exercise, after deducting the aggregate exercise price. Pursuant to their terms, immediately prior to the closing of this offering, each of these warrants will automatically be exercised on a cashless basis based upon a market price per share of our common stock equal to the per share offering price to the public in this offering, unless earlier exercised.

REGISTRATION RIGHTS

The holders of certain outstanding shares of our common stock and the holders of shares of our common stock issuable upon conversion of our convertible preferred stock, or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act. These shares are referred to as registrable securities. Upon the closing of this offering, there will be approximately 10,849,593 registrable securities outstanding. These rights are provided under the terms of an investors' rights agreement between us and the holders of these shares, which was entered into in connection with our preferred stock financings, and include demand registration rights, Form S-3 registration rights and piggyback registration rights. In any registration made pursuant to such investors' rights agreement, all fees and expenses of underwritten registrations, including reasonable fees and disbursements of one counsel to the selling stockholders, will be borne by us and all selling expenses, including estimated underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

The registration rights described below will terminate, as to each holder of registrable securities, on the date when such holder can sell all of its registrable securities in a single transaction pursuant to Rule 144 of the Securities Act.

Demand registration rights

Under the terms of the investors' rights agreement, if we receive a written request, at any time after 6 months following the effective date of this offering, from the holders of at least 35% of the then-outstanding registrable securities, that we file a registration statement under the Securities Act covering the registration of outstanding registrable securities, then we will be required to use all reasonable efforts to register, as soon as practicable, and in any event within 90 days of such written request, all of the

shares requested to be registered for public resale, if the amount of registrable securities to be registered has an aggregate value of no less than $10.0 million. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement. We may postpone the filing of a registration statement no more than once during any 12-month period for up to 90 days if our board of directors determines that the filing would be detrimental to us. We are not required to effect a demand registration under certain additional circumstances specified in the investors' rights agreement.

Form S-3 registration rights

The holders of at least 20% of the then-outstanding registrable securities can request that we register all or part of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least $1.0 million. We shall not be obligated to effect a registration if we have effected two registrations within the 12-month period immediately preceding the date of the request. We may postpone the filing of a registration statement no more than once during any 12-month period for up to 90 days if our board of directors determines that the filing would be detrimental to us or our stockholders. We are not required to effect a registration on Form S-3 under certain additional circumstances specified in the investors' rights agreement.

Piggyback registration rights

In connection with this offering, holders of our registrable securities were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their registrable securities in this offering. If we register any of our securities for public sale in another offering, holders of registrable securities will have the right to include their shares in the registration statement. However, this right does not apply to a registration relating solely to employee benefit plans, a registration relating solely to a merger, acquisition or exchange, or a registration relating to convertible debt transactions. If the total number of securities requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by us) that the underwriters in their sole discretion determine is compatible with the success of the offering, then we will be required to include in the offering only that number of securities the underwriters determine will not jeopardize the success of the offering. In this case, the number of shares held by the selling stockholders to be registered will be allocated on a pro rata basis based on the total number of registrable securities held by each selling stockholder. However, the number of shares to be registered by these holders cannot be reduced below 30% of the total shares covered by the registration statement, other than in the initial public offering.

ANTI-TAKEOVER PROVISIONS

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

Delaware law

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

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

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

Restated certificate of incorporation and restated bylaws provisions

Our restated certificate of incorporation and our restated bylaws, as we expect they will be in effect immediately prior to the closing of this offering, include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- *Board of Directors Vacancies*. Our restated certificate of incorporation and restated bylaws will authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors will be permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- *Classified Board*. Our restated certificate of incorporation and restated bylaws will provide that our board of directors will be classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors. See "Management—Board of directors."

- *Stockholder Action; Special Meetings of Stockholders*. Our restated certificate of incorporation will provide that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws and restated certificate of incorporation will provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.
- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. Our restated bylaws will provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also will specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.
- *No Cumulative Voting*. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our restated certificate of incorporation will not provide for cumulative voting.
- *Directors Removed Only for Cause*. Our restated certificate of incorporation will provide that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.
- *Amendment of Charter Provisions*. Any amendment of the above expected provisions in our restated certificate of incorporation would require approval by holders of at least two-thirds of our outstanding common stock, unless such amendment is approved by at least two-thirds of our directors, in which case the amendment may be approved by the holders of a majority of our outstanding common stock.
- *Issuance of Undesignated Preferred Stock*. Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.
- *Choice of Forum*. Our restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation or our restated bylaws; any action to interpret, apply, enforce or determine the validity of our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

EXCHANGE LISTING

We have applied to list our common stock on The NASDAQ Global Market under the symbol "OBLN."

TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is (800) 937-5449.

Shares eligible for future sale

Prior to this offering, there has not been a public market for shares of our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding options, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon the completion of this offering, we will have a total of 15,953,471 shares of our common stock outstanding, based on 10,953,471 shares outstanding as of June 30, 2016, which assumes (i) the automatic conversion of shares of our convertible preferred stock outstanding as of June 30, 2016 into an aggregate of 10,360,419 shares of our common stock immediately prior to the closing of this offering, (ii) the issuance of 12,217 shares of common stock that we expect to issue upon the automatic net exercise of warrants immediately prior to the closing of this offering, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and (iii) the sale and issuance of 5,000,000 shares of our common stock in this offering. Of these outstanding shares, all of the shares of common stock sold in this offering will be freely tradable, except that any shares purchased in this offering by our affiliates, as that term is defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, would only be able to be sold in compliance with the Rule 144 limitations described below.

The remaining outstanding shares of our common stock will be deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which rules are summarized below. In addition, substantially all of our security holders have entered into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below. As a result of these agreements and the provisions of our investors' rights agreement described above under "Description of capital stock—Registration rights," subject to the provisions of Rule 144 or Rule 701, shares will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all of the shares sold in this offering will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, 10,953,471 additional shares will become eligible for sale in the public market, of which 7,473,472 shares will be held by affiliates and subject to the volume and other restrictions of Rule 144, as described below.

The amounts above do not reflect any shares purchased by our directors and executive officers pursuant to the directed share program that will be subject to lock-up agreements or the potential purchase of any shares by certain of our stockholders and their affiliates, some of which are affiliated with our directors, pursuant to their indications of interest to purchase shares of common stock in this offering with an aggregate value of approximately $20.0 million at the initial public offering price. Additionally, the amount above does not reflect any shares purchased by participants in our directed share program who purchase $1,000,000 or more of shares of our common stock that will be subject to a 25-day lock-up period.

LOCK-UP AGREEMENTS

All of our directors and officers and the holders of more than 95% of our capital stock are subject to lock-up agreements that prohibit them from offering for sale, selling, contracting to sell, granting any option for the sale of, transferring or otherwise disposing of any shares of our common stock, options or warrants to acquire shares of our common stock or any security or instrument related to our common stock, or entering into any swap, hedge or other arrangement that transfers any of the economic consequences of ownership of our common stock, for a period of 180 days following the date of this prospectus without the prior written consent of the underwriters, subject to certain exceptions. See "Underwriting."

Participants in the directed share program who purchase $1,000,000 or more of shares of our common stock will be subject to a 25-day lock-up with respect to any shares sold to them pursuant to that program. This lock-up will have similar restrictions to the lock-up agreements described in this section. Any shares sold in the directed share program to our directors or executive officers will be subject to the lock-up agreements described in this section.

RULE 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described above, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 159,534 shares immediately after this offering; or
- the average reported weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

RULE 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are

required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701 and are subject to the lock-up agreements described above.

STOCK OPTIONS

In connection with this offering, we intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of our common stock subject to outstanding options and the shares of our common stock reserved for issuance under our stock plans. We expect to file this registration statement as soon as permitted under the Securities Act. However, the shares registered on Form S-8 may be subject to the volume limitations and the manner of sale, notice and public information requirements of Rule 144 and will not be eligible for resale until expiration of the lock-up agreements to which they are subject.

REGISTRATION RIGHTS

We have granted demand, piggyback and Form S-3 registration rights to certain of our stockholders to sell our common stock. Registration of the sale of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. For a further description of these rights, see "Description of capital stock—Registration rights."

Material U.S. federal income tax consequences to non-U.S. holders of common stock

This section summarizes the material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of our common stock by "non-U.S. holders" (as defined below) pursuant to this offering. This summary does not provide a complete analysis of all potential U.S. federal income tax considerations relating thereto. The information provided below is based upon provisions of the Internal Revenue Code of 1986, as amended, or Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions currently in effect. These authorities may change at any time, possibly retroactively, or the Internal Revenue Service, or IRS, might interpret the existing authorities differently. In either case, the tax considerations of owning or disposing of our common stock could differ from those described below. As a result, we cannot assure you that the tax consequences described in this discussion will not be challenged by the IRS or will be sustained by a court if challenged by the IRS.

This summary does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent provided below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- partnerships, or entities or arrangements treated as partnerships or other pass-through entities for U.S. federal tax purposes (or investors in such entities);
- corporations that accumulate earnings to avoid U.S. federal income tax;
- persons subject to the alternative minimum tax or the Medicare contribution tax on net investment income;
- tax-exempt organizations or tax-qualified retirement plans;
- controlled foreign corporations or passive foreign investment companies;
- persons who acquired our common stock as compensation for services;
- dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates and former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes is a beneficial owner of our common stock, the tax treatment of a partner in the partnership or an owner of

the entity will depend upon the status of the partner or other owner and the activities of the partnership or other entity. Accordingly, this summary does not address tax considerations applicable to partnerships that hold our common stock, and partners in such partnerships should consult their tax advisors.

INVESTORS CONSIDERING THE PURCHASE OF OUR COMMON STOCK SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF FOREIGN, STATE OR LOCAL LAWS, AND TAX TREATIES

NON-U.S. HOLDER DEFINED

For purposes of this summary, a "non-U.S. holder" is any holder of our common stock, other than a partnership, that is not:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state therein or the District of Columbia;
- a trust if it (1) is subject to the primary supervision of a U.S. court and one of more U.S. persons have authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person; or
- an estate whose income is subject to U.S. income tax regardless of source.

If you are a non-U.S. citizen who is an individual, you may, in many cases, be deemed to be a resident alien, as opposed to a nonresident alien, by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three- year period ending in the current calendar year. For these purposes, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year are counted. Resident aliens are subject to U.S. federal income tax as if they were U.S. citizens. Such an individual is urged to consult his or her own tax advisor regarding the U.S. federal income tax consequences of the ownership or disposition of our common stock.

DIVIDENDS

We do not expect to declare or make any distributions on our common stock in the foreseeable future and the terms of our credit facility currently restrict our ability to pay dividends. If we do pay dividends on shares of our common stock, however, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a non-U.S. holder's adjusted tax basis in shares of our common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of our common stock. See "—Sale of Common Stock."

Any dividend paid to a non-U.S. holder on our common stock that is not effectively connected with a non-U.S. holder's conduct of a trade or business in the United States will generally be subject to U.S. withholding tax at a 30% rate. The withholding tax might apply at a reduced rate under the terms of an applicable income tax treaty between the United States and the non-U.S. holder's country of residence subject to the discussion below regarding the Foreign Account Tax Compliance Act. You should consult your tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in

order for us or our paying agent to withhold tax at a lower treaty rate, a non-U.S. holder must certify its entitlement to treaty benefits. A non-U.S. holder generally can meet this certification requirement by providing a Form W-8BEN or Form W-8BEN-E (or any successor form) or appropriate substitute form to us or our paying agent. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to the agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

Dividends received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder, and if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, are attributable to a permanent establishment maintained by the non-U.S. holder in the United States, are not subject to U.S. withholding tax. To obtain this exemption, a non-U.S. holder must provide us or our paying agent with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition to being taxed at graduated tax rates, dividends received by corporate non-U.S. holders that are effectively connected with a U.S. trade or business of the corporate non-U.S. holder may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable tax treaty.

SALE OF COMMON STOCK

Subject to the discussion below regarding Backup Withholding and the Foreign Account Tax Compliance Act, non-U.S. holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange or other disposition of our common stock unless:

- the gain (i) is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business and (ii) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States (in which case the special rules described below apply);
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our common stock, and certain other requirements are met (in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States); or
- the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA, treat the gain as effectively connected with a U.S. trade or business.

The FIRPTA rules may apply to a sale, exchange or other disposition of our common stock if we are, or were within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period, a "U.S. real property holding corporation," or USRPHC. In general, we would be a USRPHC if interests in U.S. real estate comprised at least half of the value of our business assets. We do not believe that we are a USRPHC and we do not anticipate becoming one in the future. Even if we become a USRPHC, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if beneficially owned by a non-U.S. holder that actually or constructively owned more than 5% of our outstanding common stock at some time within the five-year period preceding the disposition.

If any gain from the sale, exchange or other disposition of our common stock, (i) is effectively connected with a U.S. trade or business conducted by a non-U.S. holder and (ii) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment maintained by such non-U.S. holder in the United States, then the gain generally will be subject to U.S. federal income tax at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. If the non-U.S. holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject also to a "branch profits tax." The branch profits tax rate is 30%, although an applicable income tax treaty between the United States and the non-U.S. holder's country of residence might provide for a lower rate.

U.S. FEDERAL ESTATE TAX

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and therefore will be included in the taxable estate of a nonresident alien decedent, unless an applicable estate tax treaty between the United States and the decedent's country of residence provides otherwise.

BACKUP WITHHOLDING AND INFORMATION REPORTING

The Code and the Treasury regulations require those who make specified payments to report the payments to the IRS. Among the specified payments are dividends and proceeds paid by brokers to their customers. The required information returns enable the IRS to determine whether the recipient properly included the payments in income. This reporting regime is reinforced by "backup withholding" rules. These rules require the payors to withhold tax from payments subject to information reporting if the recipient fails to cooperate with the reporting regime by failing to provide his taxpayer identification number to the payor, furnishing an incorrect identification number, or failing to report interest or dividends on his returns. The backup withholding tax rate is currently 28%. The backup withholding rules do not apply to payments to corporations, whether domestic or foreign, provided they establish such exemption.

Payments to non-U.S. holders of dividends on common stock generally will not be subject to backup withholding, and payments of proceeds made to non-U.S. holders by a broker upon a sale of common stock will not be subject to information reporting or backup withholding, in each case so long as the non-U.S. holder certifies its nonresident status (and we or our paying agent do not have actual knowledge or reason to know the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied) or otherwise establishes an exemption. The certification procedures to claim treaty benefits described under "—Dividends" will generally satisfy the certification requirements necessary to avoid the backup withholding tax. We must report annually to the IRS any dividends paid to each non-U.S. holder and the tax withheld, if any, with respect to these dividends. Copies of these reports may be made available to tax authorities in the country where the non-U.S. holder resides.

Under the Treasury regulations, the payment of proceeds from the disposition of shares of our common stock by a non-U.S. holder made to or through a U.S. office of a broker generally will be subject to information reporting and backup withholding unless the beneficial owner certifies, under penalties of perjury, among other things, its status as a non-U.S. holder (and the broker does not have actual knowledge or reason to know the holder is a U.S. person) or otherwise establishes an exemption. The payment of proceeds from the disposition of shares of our common stock by a non-U.S. holder made to or through a non-U.S. office of a broker generally will not be subject to backup withholding and information reporting, except as noted below. Information reporting, but not backup withholding, will

apply to a payment of proceeds, even if that payment is made outside of the United States, if you sell our common stock through a non-U.S. office of a broker that is:

- a U.S. person (including a foreign branch or office of such person);
- a "controlled foreign corporation" for U.S. federal income tax purposes;
- a foreign person 50% or more of whose gross income from certain periods is effectively connected with a U.S. trade or business; or
- a foreign partnership if at any time during its tax year (i) one or more of its partners are U.S. persons who, in the aggregate, hold more than 50% of the income or capital interests of the partnership or (ii) the foreign partnership is engaged in a U.S. trade or business;

unless the broker has documentary evidence that the beneficial owner is a non-U.S. holder and certain other conditions are satisfied, or the beneficial owner otherwise establishes an exemption (and the broker has no actual knowledge or reason to know to the contrary).

Backup withholding is not an additional tax. Any amounts withheld from a payment to a holder of common stock under the backup withholding rules can be credited against any U.S. federal income tax liability of the holder and may entitle the holder to a refund, provided that the required information is furnished to the IRS in a timely manner.

FOREIGN ACCOUNT TAX COMPLIANCE ACT

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds of a disposition of our common stock paid to a foreign financial institution (as specifically defined by the applicable rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to dividends and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. The 30% federal withholding tax described in this paragraph cannot be reduced under an income tax treaty with the United States or by providing an IRS Form W-8BEN or similar documentation. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. Holders should consult with their own tax advisors regarding the possible implications of the withholding described herein.

The withholding provisions described above generally apply to proceeds from a sale or other disposition of common stock if such sale or other disposition occurs on or after January 1, 2019 and to payments of dividends on our common stock.

THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE TO ANY NON-U.S. HOLDER IN ITS PARTICULAR CIRCUMSTANCES. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL AND FOREIGN TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

Underwriting

We are offering the shares of our common stock described in this prospectus through the underwriters named below. UBS Securities LLC, Canaccord Genuity Inc. and Stifel, Nicolaus & Company, Incorporated are acting as joint book-running managers of this offering and as representatives of the underwriters. We have entered into an underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase, and we have agreed to sell to the underwriters, the number of shares of common stock listed next to its name in the following table.

Underwriters	Number of shares
UBS Securities LLC	
Canaccord Genuity Inc.	
Stifel, Nicolaus & Company, Incorporated	
BTIG, LLC	
Total	5,000,000

The underwriting agreement provides that the underwriters must buy all of the shares of common stock if they buy any of them. However, the underwriters are not required to pay for the shares covered by the underwriters' option to purchase additional shares as described below.

Our common stock is offered subject to a number of conditions, including:

- receipt and acceptance of our common stock by the underwriters; and
- the underwriters' right to reject orders in whole or in part.

We have been advised by the representatives that the underwriters intend to make a market in our common stock but that they are not obligated to do so and may discontinue making a market at any time without notice.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically.

OPTION TO PURCHASE ADDITIONAL SHARES

We have granted the underwriters an option to buy up to an aggregate of 750,000 additional shares of our common stock. The underwriters have 30 days from the date of this prospectus to exercise this option. If the underwriters exercise this option, they will each purchase additional shares of common stock approximately in proportion to the amounts specified in the table above.

UNDERWRITING DISCOUNT

Shares sold by the underwriters to the public will initially be offered at the initial offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. Sales of shares made outside of the United States may be made by affiliates of the underwriters. If all the shares are not sold at the initial public offering price, the representatives may change the offering price and the other selling

terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares at the prices and upon the terms stated therein.

The following table shows the per share and total underwriting discount we will pay to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase up to 750,000 additional shares.

	No exercise	Full exercise
Per share	$	$
Total	$	$

We estimate that the total expenses of the offering payable by us, not including the underwriting discount, will be approximately $2.4 million. We have also agreed to reimburse the underwriters for certain of their expenses, including in connection with the clearance of this offering with the Financial Industry Regulatory Authority, Inc., in an amount up to $40,000.

DIRECTED SHARE PROGRAM

At our request, the underwriters have reserved up to 5% of the common stock being offered by this prospectus for sale at the initial public offering price to our directors, officers, employees and other individuals associated with us and members of their families. The sales will be made by UBS Financial Services Inc., a selected dealer affiliated with UBS Securities LLC, an underwriter of this offering, through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock. Participants in the directed share program who purchase $1,000,000 or more of shares of our common stock will be subject to a 25-day lock-up with respect to any shares sold to them pursuant to the program. This lockup will have similar restrictions to the lock-up agreements described below. Any shares sold in the directed share program to our directors or executive officers will be subject to the lock-up agreements described in "— No sales of similar securities" below.

NO SALES OF SIMILAR SECURITIES

We, our executive officers and directors, and the holders of more than 95% of our capital stock have entered into lock-up agreements with the underwriters. Under the lock-up agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of UBS Securities LLC, Canaccord Genuity Inc. and Stifel, Nicolaus & Company, Incorporated, offer, sell, contract to sell, pledge, or otherwise dispose of, directly or indirectly, or hedge our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions will be in effect for a period ending on and including the date that is 180 days after the date of this prospectus.

UBS Securities LLC, Canaccord Genuity Inc. and Stifel, Nicolaus & Company, Incorporated may, at any time and in their sole discretion, release some or all the securities from these lock-up agreements. If the restrictions under the lock-up agreements are waived, shares of our common stock may become available for resale into the market, subject to applicable law, which could reduce the market price of our common stock.

INDEMNIFICATION

We have agreed to indemnify the several underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters may be required to make in respect of those liabilities.

EXCHANGE LISTING

We have applied to list our common stock on The NASDAQ Global Market under the symbol "OBLN."

PRICE STABILIZATION, SHORT POSITIONS

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. These transactions may also include making short sales of our common stock, which involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering and purchasing shares of common stock on the open market to cover short positions created by short sales. Short sales may be "covered short sales," which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked short sales," which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or

maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on The NASDAQ Global Market, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. Neither we, nor any of the underwriters make any representation that the underwriters will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

DETERMINATION OF OFFERING PRICE

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation among us and the representatives of the underwriters. The principal factors to be considered in determining the initial public offering price include:

- the information set forth in this prospectus and otherwise available to the representatives;
- our history and prospects and the history and prospects for the industry in which we compete;
- our past and present financial performance;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities market at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

The estimated public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock or that the common stock will trade in the public market at or above the initial public offering price.

AFFILIATIONS

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and their affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of us. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

ELECTRONIC DISTRIBUTION

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters participating in this offering, or by their

affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

NOTICE TO PROSPECTIVE INVESTORS

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of common stock which are the subject of the offering contemplated by this prospectus, or Shares, may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Directive;

(b) by the underwriters to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of Shares shall result in a requirement us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. The expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

The EEA selling restriction is in addition to any other selling restrictions set out in this prospectus.

United Kingdom

This prospectus is only being distributed to and is only directed at: (1) persons who are outside the United Kingdom; (2) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order; or (3) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order, or all such persons falling within (1)-(3) together being referred to as relevant persons. The shares

are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Canada

This document constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the shares. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this document or on the merits of the shares and any representation to the contrary is an offence.

Canadian investors are advised that this document has been prepared in reliance on section 3A.3 of National Instrument 33-105 *Underwriting Conflicts*, or NI 33-105. Pursuant to section 3A.3 of NI 33-105, we and the underwriters are not required to provide investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships that may exist between the company and the underwriters as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale restrictions

The offer and sale of the shares in Canada is being made on a private placement basis only and is exempt from the requirement that we prepare and file a prospectus under applicable Canadian securities laws. Any resale of shares acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the shares outside of Canada.

Representations of purchasers

Each Canadian investor who purchases the shares will be deemed to have represented to us, the underwriters and to each dealer from whom a purchase confirmation is received, as applicable, that the investor (i) is purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws; (ii) is an "accredited investor" as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions*, or NI 45-106, or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a "permitted client" as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and eligibility for investment

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the shares and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the shares or with respect to the eligibility of the shares for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of action for damages or rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum, including where the distribution involves an "eligible foreign security" as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a "misrepresentation" as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

Australia

This prospectus is not a formal disclosure document and has not been, nor will be, lodged with the Australian Securities and Investments Commission. It does not purport to contain all information that an investor or their professional advisers would expect to find in a prospectus or other disclosure document (as defined in the Corporations Act 2001 (Australia)) for the purposes of Part 6D.2 of the Corporations Act 2001 (Australia) or in a product disclosure statement for the purposes of Part 7.9 of the Corporations Act 2001 (Australia), in either case, in relation to the securities.

The securities are not being offered in Australia to "retail clients" as defined in sections 761G and 761GA of the Corporations Act 2001 (Australia). This offering is being made in Australia solely to "wholesale clients" for the purposes of section 761G of the Corporations Act 2001 (Australia) and, as such, no prospectus, product disclosure statement or other disclosure document in relation to the securities has been, or will be, prepared.

This prospectus does not constitute an offer in Australia other than to persons who do not require disclosure under Part 6D.2 of the Corporations Act 2001 (Australia) and who are wholesale clients for the purposes of section 761G of the Corporations Act 2001 (Australia). By submitting an application for our securities, you represent and warrant to us that you are a person who does not require disclosure under Part 6D.2 and who is a wholesale client for the purposes of section 761G of the Corporations Act 2001 (Australia). If any recipient of this prospectus is not a wholesale client, no offer of, or invitation to apply for, our securities shall be deemed to be made to such recipient and no applications for our securities will be accepted from such recipient. Any offer to a recipient in Australia, and any agreement arising from acceptance of such offer, is personal and may only be accepted by the recipient. In addition, by applying for our securities you undertake to us that, for a period of 12 months from the date of issue

of the securities, you will not transfer any interest in the securities to any person in Australia other than to a person who does not require disclosure under Part 6D.2 and who is a wholesale client.

Hong Kong

The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our securities may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to "professional investors" within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the SFO and any rules made thereunder.

Japan

Our securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and our securities will not be offered or sold, directly or indirectly, in Japan, or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan, or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of our securities may not be circulated or distributed, nor may our securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where our securities are subscribed or purchased under Section 275 by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired our securities pursuant to an offer made under Section 275 except:

(1) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(2) where no consideration is or will be given for the transfer;

(3) where the transfer is by operation of law; or

(4) as specified in Section 276(7) of the SFA.

Switzerland

This Prospectus does not constitute an issue prospectus pursuant to Article 652a or Article 1156 of the Swiss Code of Obligations (CO) and the shares will not be listed on the SIX Swiss Exchange. Therefore, the Prospectus may not comply with the disclosure standards of the CO and/or the listing rules (including any prospectus schemes) of the SIX Swiss Exchange. Accordingly, the shares may not be offered to the public in or from Switzerland, but only to a selected and limited circle of investors, which do not subscribe to the shares with a view to distribution.

Greece

The securities have not been approved by the Hellenic Capital Markets Commission for distribution and marketing in Greece. This document and the information contained therein do not and shall not be deemed to constitute an invitation to the public in Greece to purchase the securities. The securities may not be advertised, distributed, offered or in any way sold in Greece except as permitted by Greek law.

Dubai International Finance Centre

This prospectus relates to an Exempt Offer in accordance with the Markets Rules of the Dubai Financial Services Authority. This prospectus is intended for distribution only to Professional Clients who are not natural persons. It must not be delivered to, or relied on by, any other person. The Dubai Financial Services Authority has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The Dubai Financial Services Authority has not approved this document nor taken steps to verify the information set out in it, and has no responsibility for it. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial adviser.

Kuwait

Unless all necessary approvals from the Kuwait Ministry of Commerce and Industry required by Law No. 31/1990 "Regulating the Negotiation of Securities and Establishment of Investment Funds," its Executive Regulations and the various Ministerial Orders issued pursuant thereto or in connection therewith, have been given in relation to the marketing and sale of the shares of common stock, the shares may not be marketed, offered for sale, nor sold in the State of Kuwait. Neither this prospectus (including any related document) nor any of the information contained herein or therein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait.

Legal matters

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Fenwick & West LLP, San Francisco, California. Certain legal matters relating to the offering will be passed upon for the underwriters by Latham & Watkins LLP, Costa Mesa, California.

Experts

The consolidated financial statements of Obalon Therapeutics, Inc. as of December 31, 2014 and 2015, and for each of the years in the two-year period ended December 31, 2015, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

Change in accountants

In October 2015, we retained KPMG LLP as our independent registered public accounting firm. Our independent auditing firm was previously Ernst & Young LLP. The decision to dismiss Ernst & Young LLP and appoint KPMG LLP was approved by our board of directors, effective as of August 4, 2015. Subsequent to KPMG LLP's appointment, we engaged KPMG LLP to reaudit our consolidated financial statements as of and for the year ended December 31, 2014, which had previously been audited by Ernst & Young LLP.

The reports of Ernst & Young LLP on our consolidated financial statements did not contain any adverse opinion or disclaimer of opinion, nor were such reports qualified or modified as to uncertainty, audit scope or accounting principles. We had no disagreements with Ernst & Young LLP on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to its satisfaction, would have caused Ernst & Young LLP to make reference in connection with its opinion to the subject matter of the disagreement during its audit of the two years ended December 31, 2014. During the two most recent fiscal years preceding our discharge of Ernst & Young LLP, and the subsequent interim period through August 4, 2015, there were no "reportable events" as such term is defined in Item 304(a)(1)(v) of Regulation S-K.

During the two years ended December 31, 2014 and through the period ended August 4, 2015, we did not consult with KPMG LLP on matters that involved the application of accounting principles to a specified transaction, either completed or proposed, the type of audit opinion that might be rendered on our financial statements or any other matter that was the subject of a disagreement as that term is used in Item 304 (a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K or a reportable event as that term is used in Item 304(a)(1)(v) and the related instructions to Item 304 of Regulation S-K.

We have provided Ernst & Young LLP with a copy of the foregoing disclosure and have requested that Ernst & Young LLP furnish us with a letter addressed to the SEC stating whether or not Ernst & Young LLP agrees with the above statements and, if not, stating the respects in which it does not agree. A copy of the letter dated August 4, 2016, furnished by Ernst & Young LLP in response to that request, is filed as an exhibit to the registration statement of which this prospectus is a part.

Additional information

We have filed with the Securities and Exchange Commission, or the SEC, a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and in each instance we refer you to the copy of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, NE, Washington, DC 20549, and copies of all or any part of the registration statement may be obtained from that office. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We currently do not file periodic reports with the SEC. Upon the closing of our initial public offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above.

We also maintain a website at www.obalon.com. Upon completion of this offering, you may access these materials at our website free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Index to consolidated financial statements

Report of Independent Registered Public Accounting Firm

The Board of Directors
Obalon Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Obalon Therapeutics, Inc. and subsidiaries as of December 31, 2014 and 2015, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2015. 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, 2014 and 2015, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

San Diego, California
May 4, 2016, except for the seventh paragraph of Note 1, as to which the date is September 23, 2016

CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and par value data)

	December 31, 2014	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 6,902	$ 3,356
Short-term investments	12,342	9,175
Accounts receivable, net	99	—
Accounts receivable, related party	155	636
Inventory	445	363
Other current assets	293	273
Total current assets	20,236	13,803
Property and equipment, net	483	418
Total assets	$ 20,719	$ 14,221
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 181	$ 549
Accrued compensation	239	1,250
Accrued clinical expenses	15	913
Other current liabilities	381	493
Customer deposit from related party	—	1,283
Current portion of long-term loan	—	747
Warrant liability	56	332
Total current liabilities	872	5,567
Long-term loan, excluding current portion	4,877	9,094
Total liabilities	5,749	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, 804,595 shares issued and outstanding at December 31, 2014 and 2015, respectively; liquidation preference of $7,000	6,773	6,773
Series B convertible preferred stock, $0.001 par value; 4,333,332 shares authorized, 1,494,248 shares issued and outstanding at December 31, 2014 and 2015, respectively; liquidation preference of $6,500	6,454	6,454
Series C convertible preferred stock, $0.001 par value; 7,809,939 shares authorized, 2,668,533 shares issued and outstanding at December 31, 2014 and 2015, respectively; liquidation preference of $16,523	16,393	16,393
Series C-1 convertible preferred stock, $0.001 par value; 2,783,334 shares authorized, 480,286 shares issued and outstanding at December 31, 2014 and 2015, respectively; liquidation preference of $5,000	4,984	4,984
Series D convertible preferred stock, $0.001 par value; 11,546,013 shares authorized, 2,732,552 shares issued and outstanding at December 31, 2014 and 2015, respectively; liquidation preference of $41,180	20,222	20,095
	54,826	54,699

	December 31, 2014	December 31, 2015
Stockholders' deficit:		
Common stock, par value $0.001; 35,000,000 shares authorized, 533,484 and 575,126 shares issued and outstanding at December 31, 2014 and 2015, respectively	1	1
Additional paid-in capital	733	1,002
Other comprehensive (loss) income	(5)	—
Accumulated deficit	(40,585)	(56,142)
Total stockholders' deficit	(39,856)	(55,139)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 20,719	$ 14,221

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2014	2015
Revenue:		
Revenue	$ 1,683	$ 216
Revenue, related party	1,856	3,823
Total revenue	3,539	4,039
Cost of revenue	2,912	2,503
Gross profit	627	1,536
Operating expenses:		
Research and development	5,767	12,978
Selling, general and administrative	4,700	3,491
Total operating expenses	10,467	16,469
Loss from operations	(9,840)	(14,933)
Interest expense, net	(220)	(549)
Gain (loss) from change in fair value of warrant liability	167	(34)
Other income (expense), net	3	(41)
Net loss	(9,890)	(15,557)
Other comprehensive income	9	5
Net loss and comprehensive loss	$ (9,881)	$ (15,552)
Net loss per share, basic and diluted	$ (18.61)	$ (27.14)
Weighted-average common shares outstanding, basic and diluted	531,430	573,181
Pro forma net loss per share, basic and diluted (unaudited)		$ (1.72)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)		9,026,927

See accompanying notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
Years ended December 31, 2014 and 2015
(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		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				
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)

See accompanying notes to consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,	
	2014	2015
Operating activities:		
Net loss	$ (9,890)	$(15,557)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	166	167
Stock-based compensation	185	207
Loss on disposal of fixed assets	5	19
Change in fair value of warrant liability	(167)	34
Amortization (accretion) of investment premium (discount), net	64	260
Amortization of debt discount	41	79
Change in operating assets and liabilities:		
Accounts receivable, net	83	96
Accounts receivable from related party	4	(481)
Inventory	(166)	77
Other current assets	(109)	27
Accounts payable and accrued expenses	(33)	370
Accrued compensation	33	1,018
Accrued clinical expenses	(129)	898
Other current liabilities	6	111
Customer deposit from related party	—	1,283
Net cash used in operating activities	(9,907)	(11,392)
Investing activities:		
Purchases of short-term investments	(12,400)	(18,590)
Maturities of short-term investments	4,250	21,500
Sales of short-term investments	500	—
Purchase of property and equipment	(268)	(139)
Proceeds from disposal of property and equipment	—	6
Net cash (used in) provided by investing activities	(7,918)	2,777
Financing activities:		
Issuance of preferred stock for cash, net of offering costs	13,622	—
Issuance of preferred stock to related party for cash	6,600	—
Proceeds from long-term loan, net of issuance costs	4,958	5,000
Repayments on long-term loan	(3,000)	—
Sale of common stock	8	62
Net cash provided by financing activities	22,188	5,062
Effect of exchange rate changes on cash and cash equivalents	12	7
Net increase (decrease) in cash and cash equivalents	4,375	(3,546)
Cash and cash equivalents at beginning of period	2,527	6,902
Cash and cash equivalents at end of period	$ 6,902	$ 3,356
Supplemental cash flow information:		
Interest paid	$ 164	$ 475
Income taxes paid	$ 1	$ 2

See accompanying notes to consolidated financial statements.

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 commercial-stage medical device company focused on developing and commercializing innovative medical devices to treat obese and overweight people by facilitating weight loss. Using its patented technology, the Company has developed the Obalon balloon system, the first swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese and overweight 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. 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. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern.

As of December 31, 2015, 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 $3.5 million and $4.0 million for the years ended December 31, 2014 and 2015, respectively. Prior to 2014, the Company was considered to be in the development stage. 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. As of December 31, 2015, the Company had not yet obtained U.S. Food and Drug Administration, or FDA, approval to sell its products in the United States. All sales are to customers outside of the United States, mainly in the Middle East.

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 experienced net losses since its inception and, as of December 31, 2015, had an accumulated deficit of $56.1 million. Based on the Company's current plan of expenditures for its research and development, clinical trial, and other operating costs, the Company expects to continue to incur net losses for the foreseeable future. Over that period, the Company may need to raise additional debt or equity financing to fund its operations. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, suspend or curtail planned programs, and/or cease operations. Any of these actions could materially harm the Company's business, results of operations, financial condition, and future prospects. The Company believes that cash and short-term investments, including the additional amounts raised as described in note 12 are sufficient to satisfy the Company's operations for at least the next twelve months.

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.

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. Significant items subject to such estimates and assumptions include the warrant liability, stock-based compensation, and income tax uncertainties.

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.

Foreign Currency

The functional currency of a foreign operation is considered to be the local country's currency. Consequently, assets and liabilities of operations outside the United States are translated into U.S. dollars, and the effects of foreign currency translation adjustments are included as a component of accumulated other comprehensive loss.

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, 2014 and 2015, 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, 2014 and 2015. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Fair Value Measurements

The carrying values of the Company's financial instruments, including cash and cash equivalents, accounts receivable, 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 $0.1 million and $0 at December 31, 2014 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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,	
	2014	2015
Single largest customer:		
Revenue, related party	52.4%	94.7%
Accounts receivable, related party	61.0%	100.0%
Second largest customer:		
Revenue	10.0%	N/A
Accounts receivable	2.6%	N/A

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 life of software
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 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, 2014 and 2015.

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.

Stock-based awards and stock options issued to nonemployee consultants are recorded at fair value and remeasured at the end of each period as they vest using the Black-Scholes option pricing model. Expense is recognized over the vesting period, which is generally the same as the service period.

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 accrual as of December 31, 2014 and 2015 was immaterial and was included in other current liabilities.

Advertising Costs

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

Preferred Stock Warrants

The fair value of preferred stock warrants issued in conjunction with debt issuances is initially recorded as a warrant liability and debt discount. The fair value of preferred stock warrants issued in conjunction with equity financing is initially recorded as a warrant liability and reduction of the proceeds received. The fair value of the warrants is 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, and expected dividends and expected volatility of the price of the underlying preferred stock. The warrant liability is remeasured each reporting period with changes in fair value being recognized in the consolidated statements of operations and comprehensive loss. 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.

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

(Unaudited) Pro Forma Net Loss per Share

Pro forma basic and diluted net loss per share has been computed to give effect to: (i) the assumed conversion of the shares of convertible preferred stock into common stock; (ii) the automatic net exercise of certain outstanding warrants to purchase shares of preferred stock; and (iii) the automatic conversion of certain outstanding warrants to purchase shares of preferred stock into warrants to purchase shares of common stock as if such conversions had occurred at the beginning of the period. The pro forma net loss does not include the shares expected to be sold and related proceeds to be received from an initial public offering, or IPO.

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 May 2014, the FASB issued Accounting Standard Update, or ASU, 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. ASU 2014-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016. Entities are able to use one of three prescribed transition methods. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. The Company has not yet selected a transition method as the Company is currently evaluating the impact of the amended revenue recognition guidance on its consolidated financial statements.

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 fiscal years ending after December 15, 2016. The Company does not anticipate that the adoption of ASU 2014-15 will have a material impact on its consolidated financial statements.

In April 2015, FASB issued ASU 2015-03, *Interest—Imputation of Interest*. This simplifies the presentation of debt issuance costs by requiring them to be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability. ASU 2015-03 is effective for financial statements issued for fiscal years beginning after December 15, 2015. The Company had previously presented debt issuance costs as a direct deduction from the carrying amount of its debt liabilities. As such, the Company has early adopted the provisions of ASU 2015-03 for the years ended December 31, 2014 and 2015.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 (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 fiscal years beginning after December 31, 2016 with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect that the adoption of this guidance will have a significant impact on the Company's financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, an update to Accounting Standards Codification (ASC) 740, *Income Taxes*. Current GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update.

For nonpublic business entities, the amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The FASB also decided to permit earlier application by all entities as of the beginning of any interim or annual reporting period. The FASB further provides that this update may be applied to all deferred tax liabilities and assets prospectively. The Company adopted this update prospectively beginning in the year ended December 31, 2015. No prior periods were retrospectively adjusted.

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 as of December 31, 2014 and 2015 are as follows (in thousands):

		Fair value measurements at reporting date using		
	Balance as of December 31, 2014	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)	$ 6,588	$ 6,588	$ —	$ —
U.S. Treasury bonds(2)	12,342	12,342	—	—
Total assets	$18,930	$18,930	$ —	$ —
Liabilities:				
Warrant liability	$ 56	$ —	$ —	$ 56
Total liabilities	$ 56	$ —	$ —	$ 56

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	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, 2014 and 2015.

The warrant liability is recorded at fair value using the Black-Scholes option pricing model based on the following assumptions as of December 31, 2014 and 2015:

	December 31, 2014	December 31, 2015
Assumed risk-free interest rate	1.38% - 2.17%	1.28% - 2.06%
Assumed volatility	54.48% - 72.90%	66.76% - 70.66%
Expected life	4.15 - 9.75 yrs	3.15 - 8.75 yrs
Expected dividend yield	—%	—%
Preferred stock fair value:		
Series D	$ 7.54	$ 8.41
Series C-1	$ 1.80	$ 2.24
Series C	$ 1.40	$ 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Preferred stock fair value — Given the absence of a public trading market, 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 initial public offering or a merger or acquisition of the Company, given prevailing market conditions.

As of December 31, 2014 and 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, 2014 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, 2014 and 2015 (in thousands):

	Fair value measurements at reporting date using significant unobservable inputs (Level 3)
Balance at December 31, 2013	$ 177
Issuance of warrants for the purchase of convertible preferred stock	46
Change in fair value of warrant liability	(167)
Balance at December 31, 2014	56
Issuance of warrants for the purchase of convertible preferred stock	242
Change in fair value of warrant liability	34
Balance at December 31, 2015	$ 332

Instruments Not Recorded at Fair Value on a Recurring Basis

The estimated fair value of long-term debt 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 debt approximates the current fair value because of its relatively short maturity date.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Net Loss per Share and (Unaudited) Pro Forma 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,	
	2014	2015
Net loss	$ (9,890)	$ (15,557)
Weighted-average shares used in computing net loss per share	531,430	573,181
Net loss per share, basic and diluted	$ (18.61)	$ (27.14)

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,	
	2014	2015
Convertible preferred stock, on an as-converted basis	6,654,734	8,443,994
Stock options to purchase common stock	59,438	—
Total	6,714,172	8,443,994

The following table summarizes our pro forma net loss per share (in thousands, except shares and per share data):

	Year ended December 31, 2015
Numerator:	
Net loss	$ (15,557)
Change in fair value of convertible preferred stock warrants	34
Pro forma net loss (unaudited)	$ (15,523)
Denominator:	
Weighted-average shares used in computing net loss per share, basic and diluted	573,181
Pro forma adjustments to reflect assumed conversion of convertible preferred stock	8,443,994
Pro forma adjustments to reflect assumed conversion of convertible preferred stock warrants	9,752
Weighted-average shares used in computing pro forma net loss per share, basic and diluted	9,026,927
Pro forma net loss per share, basic and diluted (unaudited)	$ (1.72)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

5. Balance Sheet Details

Short-term investments consist of the following at December 31, 2014 and 2015 (in thousands):

	Maturity (in years)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
At December 31, 2014:					
U.S. Treasury	1 year or less	$ 12,348	$ —	$ (6)	$ 12,342

	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,	
	2014	2015
Raw materials	$ 207	$ 235
Work in process	204	121
Finished goods	34	7
Total	$ 445	$ 363

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

	December 31,	
	2014	2015
Prepaid assets	$ 234	$ 234
Interest receivable	59	25
Other assets	—	14
Total	$ 293	$ 273

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

	December 31,	
	2014	2015
Computer equipment	$ 247	$ 255
Leasehold improvements	172	181
Furniture and fixtures	76	82
Scientific equipment	636	770
Construction in progress, or CIP	79	24
	1,210	1,312
Less: accumulated depreciation and amortization	(727)	(894)
Total	$ 483	$ 418

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

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

	December 31,	
	2014	2015
Accrued legal	$ 49	$162
Accrued professional fees	156	195
Accrued interest	21	44
Other accrued expenses	155	92
Total	$381	$493

6. Term Loan

In June 2013, the Company entered into a loan and security agreement, or 2013 Loan Agreement, with Square 1 Bank allowing for borrowings up to $3.0 million. In addition to the interest payments, Square 1 Bank received warrants for the purchase of up to 8,693 shares of the Company's Series C-1 convertible preferred stock. In October 2014, the Company amended the 2013 Loan Agreement and executed a $10.0 million credit facility with Square 1 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 Square 1 Bank additional warrants to purchase up to 27,869 shares of its Series D convertible preferred stock at $7.5351 per share.

The present value of the future cash flows under the 2014 Loan Agreement terms described below 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 are amortized to interest expense over the remaining term of the 2014 Loan Agreement using the effective-interest method.

The interest rate under the 2014 Loan Agreement is at a variable annual rate equal to the greater of the prime rate plus 1.75% or 5.0%, and there is an interest-only period until October 31, 2016, followed by a 24-month principal and interest period. Pursuant to the 2014 Loan Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property owned by the Company. As of December 31, 2015, unpaid borrowings under the 2014 Loan Agreement totaled $10.0 million. For the year ended December 31, 2014, the Company recorded an immaterial amount related to the amortization of debt discount and $0.1 million for the year ended December 31, 2015.

The 2014 Loan Agreement includes restrictions on, among other things, the Company's ability to incur additional indebtedness, change the name or location of the Company's business, merge with or acquire

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

other entities, pay dividends or make other distributions to holders of its capital stock, make certain investments, engage in transactions with its affiliates, create liens, sell assets, pay subordinated debt, and store certain inventory and equipment with third parties. The 2014 Loan Agreement also requires that, if the Company's total cash is less than $5.0 million, the Company is required to maintain all its deposits, transaction accounts and primary investment accounts with Square 1 Bank, and if the Company's total cash is greater than $5.0 million, it is required to maintain 50% of its deposits, transaction accounts and primary investment accounts with Square 1 Bank.

As of December 31, 2015, future principal payments due under the 2014 Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2016	$ 833
December 31, 2017	5,000
December 31, 2018	4,167
Total future principal payments due under the 2014 Loan Agreement	$10,000

7. Stock-Based Compensation

The Company adopted an Equity Incentive Plan, or the Plan, in 2008, under which 1,552,487 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.

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. As of December 31, 2015, 94,663 options remained available for future grant under the Plan.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the assumptions noted in the following table. 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 expected life of options is based on the simplified method, which is an average of the contractual term of the options and its ordinary vesting period. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of commercial development. The risk-free interest rate is based on the average yield of U.S. Treasury bills as of the valuation date for the expected

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

term of the award. 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,	
	2014	2015
Assumed risk-free interest rate	1.82% - 2.09%	1.57%
Assumed volatility	71.09%	61.53%
Expected option life	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,	
	2014	2015
Cost of revenue	$ 30	$ 31
Research and development	45	47
Selling, general and administrative	110	129
Total	$185	$207

Unrecognized compensation expense at December 31, 2015 was approximately $0.3 million, which is expected to be recognized over a weighted-average term of 2.3 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, 2014 and 2015.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table summarizes stock option transactions for the Plan for the years ended December 31, 2014 and 2015 (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, 2013	926,437	$ 1.75		
Options granted	116,545	2.12		
Options exercised	(4,285)	1.96		
Options canceled	(108,019)	1.89		
Outstanding at December 31, 2014	930,678	1.78		
Options granted	448,809	0.76		
Options exercised	(41,642)	1.52		
Options canceled	(38,977)	1.77		
Outstanding at December 31, 2015	1,298,868	$ 1.44	7.0	$ (747)
Vested and expected to vest, December 31, 2015	1,216,907	$ 1.51	7.0	$ (733)
Vested and exercisable, December 31, 2015	700,578	$ 1.74	6.0	$ (585)

The weighted-average fair value of options granted during the years ended December 31, 2015 was $0.44. All options outstanding at year-end are exercisable under the early exercise provisions of the Plan. The intrinsic value of options exercised for the years ended December 31, 2014 and 2015 was immaterial.

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 years ended December 31, 2014 and 2015, no options were early exercised.

8. Convertible Preferred Stock and Stockholders' Deficit

Convertible Preferred Stock

During 2008, the Company entered into agreements with several investors who collectively purchased 804,595 shares of Series A convertible preferred stock at $8.70 per share for cash proceeds of $7.0 million, gross of $0.2 million in issuance costs.

During 2009, the Company entered into agreements with several investors who collectively purchased 689,651 shares of Series B convertible preferred stock at $4.35 per share for cash proceeds of $3.0 million, gross of immaterial issuance costs. During 2011, the Company entered into agreements with several investors who collectively purchased 804,597 shares of Series B preferred stock at $4.35 per share for cash proceeds of $3.5 million, gross of immaterial issuance costs.

During 2012, the Company entered into agreements with several investors who collectively purchased 2,668,533 shares of Series C convertible preferred stock at $6.1918 per share for cash proceeds of $15.0 million, gross of $0.1 million in issuance costs, and converted approximately $2.0 million in convertible debt into shares of Series C preferred stock. In conjunction, warrants were issued for 24,224 shares of Series C preferred stock. All the warrants remain outstanding as of December 31, 2015.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

During 2012, the Company entered into agreements with several investors for the purchase of 480,286 shares of Series C-1 convertible preferred stock at $10.4105 per share for cash proceeds of $5.0 million, gross of immaterial issuance costs.

During 2013, the Company entered into a loan and security agreement with Square 1 Bank, issuing a warrant for 8,693 shares of Series C-1 preferred stock. The warrant remains outstanding as of December 31, 2015.

During 2014, the Company entered into agreements with several investors for the purchase of 2,732,552 shares of Series D convertible preferred stock at $7.5351 per share for cash proceeds of $20.6 million, gross of $0.5 million in issuance costs, of which $0.1 million is for the value of warrants. In conjunction, a warrant was issued to Square 1 Bank for 27,869 shares of Series D convertible preferred stock. During 2015, warrants were issued to investors for 24,550 shares of Series D preferred stock. All the warrants remain outstanding as of December 31, 2015.

Preferred stock is separated into two classes, Series D convertible preferred stock and Junior preferred stock. Junior preferred stock is comprised of Series A, Series B, Series C, and Series C-1 convertible preferred stock. Holders of Series D and Junior preferred stock are entitled to receive dividends, if declared by the board of directors, at rate of $0.6960 per annum for Series A shares, $0.3480 per annum for Series B shares, $0.4350 per annum for Series C shares, $0.8326 per annum for Series C-1 shares, and $0.6029 per annum for Series D shares. Dividends are paid in preference and priority to holders of Series D convertible preferred stock, then to holders of Junior preferred stock and lastly to holders of common stock. As of December 31, 2015, the Company's board of directors has not declared any dividends.

In the event of liquidation, the holders of preferred stock are entitled to receive liquidation preferences at the rate of $8.70 per share for Series A shares, $4.35 per share for Series B shares, $6.1918 per share for Series C shares, $10.4105 per share for series C-1 shares, and $15.0701 per share for Series D shares. The holders of Series D convertible preferred stock are entitled to receive first preference on any liquidation distributions. Liquidation distributions to holders of Junior preferred stock are made pari passu and are made in preference to any payments to the holders of common stock. Preferred stock holders participate without limit with the holders of common stock for up to two times such preferred stock's original issue price.

The shares of preferred stock are convertible into shares of common stock, at the option of the holder, subject to certain anti-dilution adjustments. Each share of Series A convertible preferred stock is convertible to 1.32784 shares of common stock and each share of Series B, Series C, Series C-1 and Series D convertible preferred stock is convertible to one share of common stock. Each share of preferred stock is automatically converted into common stock immediately upon 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 $11.3025 (as adjusted). Each share of Series D convertible preferred stock is automatically converted into common stock immediately upon the affirmative vote of more than 67% of the holders of the then-outstanding Series D stock. Each share of Junior preferred stock is automatically converted into common stock immediately upon the affirmative vote of more than 67% of the holders of the then-outstanding Junior preferred stock voting together as a single class.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The convertible preferred stock has been classified as temporary equity in the accompanying balance sheets as the shares include provisions allowing the holder to cause redemption of the shares upon certain changes in control events that are outside of the Company's control.

The holders of Preferred Stock are entitled to one vote for each share of common stock into which such Preferred Stock could then be converted; and with respect to such vote, such holders shall have full voting rights and powers equal to the voting rights and powers of the holders of common stock.

Outstanding Warrants

At December 31, 2015, the following warrants were outstanding:

	Shares	Weighted-average exercise price	Issuance date	Expiration date
Series C	24,224	$6.1918	Feb 24, 2012	Feb 24, 2019
Series C-1	8,693	10.36	Jun 14, 2013	Jun 14, 2023
Series D	27,869	7.5351	Oct 01, 2014	Oct 01, 2024
Series D	7,962	7.5351	Mar 15, 2015	Mar 15, 2023
Series D	16,588	7.5351	Mar 16, 2015	Mar 16, 2023
Total shares	85,336	$7.4408		

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2015:

Conversion of preferred stock	8,443,994
Stock options issued and outstanding	1,298,868
Authorized for future option grants	94,663
Warrants outstanding	85,336
Total	9,922,861

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

9. Income Taxes

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

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

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

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

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 382/383 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 $11.5 million and research and experimental credits of approximately $2.1 million generated through 2015 from its deferred tax schedule, and has recorded a corresponding decrease to its valuation allowance.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	Year ended December 31,	
	2014	2015
Deferred tax assets:		
Foreign net operating losses	$ 390	$ 388
Capitalized research and development	3,160	7,420
Other	114	111
Total gross deferred tax assets	3,664	7,919
Less valuation allowance	(3,664)	(7,919)
Total deferred tax assets	$ —	$ —

A valuation allowance of $3.7 million and $7.9 million as of December 31, 2014 and 2015, respectively, has been established to offset the deferred tax assets as realization of such assets are uncertain.

At December 31, 2015, the Company had federal, state, and foreign tax net operating loss carryforwards of approximately $31.5 million, $13.9 million, and $1.3 million, respectively. Each of the federal and state tax loss carryforwards will begin expiring in 2028, unless previously utilized. The foreign net operating losses, or NOLs, will begin expiring in 2023, unless previously utilized. The Company also has federal and California research and development tax credit carryforwards totaling $1.3 million and $1.1 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. The Company has currently adjusted its California NOLs and deferred tax assets to the Single Sales Factor state rate. The impact to the California NOLs is approximately $10.2 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, 2014 and 2015, 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, 2014 and 2015, the foreign subsidiaries do not have cumulative earnings. As of December 31, 2015, one of these entities had been dissolved and another was in the process of being 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, 2014 and 2015, we 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. We do not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

10. Commitments and Contingencies

The Company's building lease will expire on March 31, 2017. Future minimum payments due under the noncancelable operating lease are as follows (in thousands):

Year ended:	
December 31, 2016	$225
December 31, 2017	54
Total future payments due under building lease	$279

Rent expense totaled $0.2 million for both years ended December 31, 2014 and 2015.

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 an exclusive distributor of its products in the Middle East. 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, and will thereafter automatically renew for successive terms of 12 months, subject to certain exceptions. 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, 2014 and 2015 totaled $1.9 million and $3.8 million, respectively, which represent 52.4% and 94.7% of total revenue for the respective years. As of December 31, 2015, the Company had accounts receivable from Bader of $0.6 million.

In December 2014, 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.

As discussed in note 12, in April 2016, the Company and Bader entered into a payment direction letter, resulting in the exchange of the distribution agreement deposit for Series E convertible preferred stock.

12. Subsequent Events

The Company has evaluated subsequent events through May 4, 2016, which is the date on which the financial statements were available to be issued.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

On April 29, 2016, the Company completed the initial closing of its Series E convertible preferred stock financing and issued 1,910,379 shares of Series E convertible preferred stock for total proceeds of $15.8 million. Included in these proceeds was the exchange of Bader's $1.3 million deposit for the preferred stock.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except shares and par value data)

	December 31, 2015	June 30, 2016	Pro Forma Stockholders' Equity June 30, 2016
		(unaudited)	(unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 3,356	$ 4,329	
Short-term investments	9,175	13,953	
Accounts receivable, related party	636	585	
Inventory	363	477	
Other current assets	273	215	
Total current assets	13,803	19,559	
Property and equipment, net	418	512	
Total assets	$ 14,221	$ 20,071	
Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity			
Current liabilities:			
Accounts payable and accrued expenses	$ 549	$ 733	
Accrued compensation	1,250	236	
Accrued clinical expenses	913	612	
Other current liabilities	493	586	
Customer deposit from related party	1,283	—	
Current portion of long-term loan	747	3,255	
Warrant liability	332	213	
Total current liabilities	5,567	5,635	
Long-term loan, excluding current portion	9,094	6,628	
Total liabilities	14,661	12,263	
Commitments and contingencies (See Note 10)			
Convertible preferred stock			
Series A convertible preferred stock, $0.001 par value; 2,333,332 shares authorized, 804,595 shares issued and outstanding at December 31, 2015 and June 30, 2016, respectively; liquidation preference of $7,000 at December 31, 2015 and June 30, 2016, actual; no shares issued and outstanding at June 30, 2016, pro forma	6,773	6,773	—
Series B convertible preferred stock, $0.001 par value; 4,333,332 shares authorized, 1,494,248 shares issued and outstanding at December 31, 2015 and June 30, 2016, respectively; liquidation preference of $6,500 at December 31, 2015 and June 30, 2016, actual; no shares issued and outstanding at June 30, 2016, pro forma	6,454	6,454	—

	December 31, 2015	June 30, 2016	Pro Forma Stockholders' Equity June 30, 2016
		(unaudited)	(unaudited)
Series C convertible preferred stock, $0.001 par value; 7,809,939 and 7,809,006 shares authorized at December 31, 2015 and June 30, 2016, respectively; 2,668,533 shares issued and outstanding at December 31, 2015 and June 30, 2016, respectively; liquidation preference of $16,523 at December 31, 2015 and June 30, 2016, actual; no shares issued and outstanding at June 30, 2016, pro forma	16,393	16,393	—
Series C-1 convertible preferred stock, $0.001 par value; 2,783,334 and 1,418,042 shares authorized at December 31, 2015 and June 30, 2016, respectively 480,286 shares issued and outstanding at December 31, 2015 and June 30, 2016; liquidation preference of $5,000 at December 31, 2015 and June 30, 2016, actual; no shares issued and outstanding at June 30, 2016, pro forma	4,984	4,984	—
Series D convertible preferred stock, $0.001 par value; 11,546,013 and 8,076,436 shares authorized at December 31, 2015 and June 30, 2016, respectively, 2,732,552 shares issued and outstanding at December 31, 2015 and June 30, 2016; liquidation preference of $41,180 and $20,590 at December 31, 2015 and June 30, 2016, respectively, actual; no shares issued and outstanding at June 30, 2016, pro forma	20,095	20,095	—
Series E convertible preferred stock, $0.001 par value; 0 and 10,490,611 shares authorized at December 31, 2015 and June 30, 2016, respectively; 0 and 1,916,425 shares issued and outstanding at December 31, 2015 and June 30, 2016, respectively; liquidation preference of $0 and $15,893 at December 31, 2015 and June 30, 2016, respectively, actual, no shares issued and outstanding at June 30, 2016, pro forma	—	15,799	—
	54,699	70,498	
Stockholders' (deficit) equity:			
Common stock, par value $0.001; 35,000,000 and 45,000,000 shares authorized at December 31, 2015 and June 30, 2016, respectively; 575,126 and 580,835 shares issued and outstanding at December 31, 2015 and June 30, 2016, respectively; 10,953,471 shares issued and outstanding at June 30, 2016, pro forma	1	1	11
Additional paid-in capital	1,002	1,159	71,979
Other comprehensive income	—	4	4
Accumulated deficit	(56,142)	(63,854)	(63,973)
Total stockholders' (deficit) equity	(55,139)	(62,690)	8,021
Total liabilities and stockholders' (deficit) equity	$ 14,221	$ 20,071	$ 20,071

See accompanying notes to condensed consolidated financial statements.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except shares and per share data)

	Six months ended June 30,	
	2015	2016
Revenue:		
Revenue	$ 224	$ —
Revenue, related party	1,739	1,848
Total revenue	1,963	1,848
Cost of revenue	1,205	1,294
Gross profit	758	554
Operating expenses:		
Research and development	5,968	5,098
Selling, general and administrative	1,679	2,975
Total operating expenses	7,647	8,073
Loss from operations	(6,889)	(7,519)
Interest expense, net	(263)	(290)
Gain from change in fair value of warrant liability	11	119
Other expense, net	(16)	(22)
Net loss	(7,157)	(7,712)
Other comprehensive income	10	4
Net loss and comprehensive loss	$ (7,147)	$ (7,708)
Net loss per share, basic and diluted	$ (12.51)	$ (13.37)
Weighted-average common shares outstanding, basic and diluted	572,195	576,757
Pro forma net loss per share, basic and diluted		$ (0.81)
Pro forma weighted-average common shares outstanding, basic and diluted		9,691,211

See accompanying notes to condensed consolidated financial statements.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Six months ended June 30,	
	2015	2016
Operating activities:		
Net loss	$ (7,157)	$ (7,712)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	81	90
Stock-based compensation	100	145
Loss on disposal of fixed assets	2	13
Change in fair value of warrant liability	(11)	(119)
Amortization (accretion) of investment premium (discount), net	152	55
Amortization of debt discount	36	43
Change in operating assets and liabilities:		
Accounts receivable, net	96	—
Accounts receivable from related party	(619)	51
Inventory	168	(114)
Other current assets	54	46
Accounts payable and accrued expenses	97	60
Accrued compensation	53	(1,014)
Accrued clinical expenses	2,053	(301)
Other current liabilities	160	94
Customer deposit from related party	1,283	—
Net cash used in operating activities	(3,452)	(8,663)
Investing activities:		
Purchases of short-term investments	(10,691)	(14,979)
Maturities of short-term investments	4,200	10,150
Purchase of property and equipment	(58)	(63)
Net cash used in investing activities	(6,549)	(4,892)
Financing activities:		
Issuance of preferred stock for cash, net of offering costs	—	14,517
Proceeds from long-term loan, net of issuance costs	5,000	—
Sale of common stock	59	11
Net cash provided by financing activities	5,059	14,528
Net (decrease) increase in cash and cash equivalents	(4,942)	973
Cash and cash equivalents at beginning of period	6,902	3,356
Cash and cash equivalents at end of period	$ 1,960	$ 4,329
Supplemental cash flow information:		
Interest paid	$ 241	$ 266
Non-cash investing and financing activities:		
Conversion of customer deposit from related party to preferred stock	$ —	$ 1,283
Property and equipment in accounts payable	$ —	$ 121

See accompanying notes to condensed consolidated financial statements.

NOTES TO UNAUDITED INTERIM CONDENSED 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 commercial-stage medical device company focused on developing and commercializing innovative medical devices to treat obese and overweight people by facilitating weight loss. Using its patented technology, the Company has developed the Obalon balloon system, the first swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese and overweight 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. All intercompany balances and transactions have been eliminated in consolidation.

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

As of June 30, 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 $1.8 million for the six months ended June 30, 2016, respectively. Prior to 2014, the Company was considered to be in the development stage. However, the Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and has funded its activities to date almost exclusively from debt and equity financings. As of June 30, 2016, the Company had not yet obtained FDA approval to sell its products in the United States. All sales are to customers outside of the United States, mainly in the Middle East.

As reflected in the accompanying condensed 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 June 30, 2016, its accumulated deficit was $63.9 million. Since inception, the Company has financed its operations primarily through private placements of preferred securities 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, seeks regulatory approval, prepares for and, if approved, proceeds to, commercialization of its product in the United States and continues research and development efforts. The Company will need additional funding to pay expenses relating to its operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to the Company on acceptable terms, or at all. The failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations or financial condition.

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.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

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. Significant items subject to such estimates and assumptions include the warrant liability, stock-based compensation, and income tax uncertainties.

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.

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated financial statements as of June 30, 2016 and for the six months ended June 30, 2015 and 2016 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed consolidated financial position as of June 30, 2016 and its consolidated results of operations and cash flows for the six months ended June 30, 2015 and 2016. The financial data and other information disclosed in these notes to consolidated financial statements related to the six-month periods are also unaudited. The results of operations for the six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other future annual or interim period. The balance sheet as of December 31, 2015 included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company's audited financial statements included elsewhere in this prospectus.

Unaudited Pro Forma Stockholders' Equity

The unaudited pro forma stockholders' equity as of June 30, 2016 assumes: (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2016 into shares of common stock immediately prior to the closing of this offering; (ii) the automatic net exercise of certain outstanding warrants to purchase shares of preferred stock immediately prior to the closing of this offering, which will result in the issuance of 12,217 shares of common stock, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the related reclassification of the warrant liability to stockholders' equity; (iii) the automatic conversion of certain outstanding warrants to purchase shares of preferred stock into warrants to purchase shares of common stock upon the closing of this offering and the related reclassification of the warrant liability to additional paid-in capital. The pro forma balance sheet was prepared as though the completion of the IPO contemplated by this prospectus had occurred on June 30, 2016. Shares of common stock issued in the IPO and any related net proceeds are excluded from the pro forma information.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

Short-Term Investments

The Company classifies its investments as available-for-sale and records such assets at estimated fair value in 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 six months ended June 30, 2015 and 2016, unrealized losses were immaterial. 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 six months ended June 30, 2015 or 2016. 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, 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 are currently available to the Company.

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

- Level 1 inputs: Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

Deferred Initial Public Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to the IPO, are capitalized. The deferred offering costs will be offset against IPO proceeds upon the consummation of the offering. In the event the offering is terminated, deferred offering costs will be expensed. As of June 30, 2016, an immaterial amount of deferred offering costs have been incurred. No deferred offering costs were capitalized as of December 31, 2015.

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.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

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.

Unaudited Pro Forma Net Loss per Share

Pro forma basic and diluted net loss per share has been computed to give effect to: (i) the assumed conversion of the shares of convertible preferred stock into common stock; (ii) the automatic net exercise of certain outstanding warrants to purchase shares of preferred stock; and (iii) the automatic conversion of certain outstanding warrants to purchase shares of preferred stock into warrants to purchase shares of common stock as if such conversions had occurred at the beginning of the period. The pro forma net loss does not include the shares expected to be sold and related proceeds to be received from an initial public offering, or IPO.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standard Update, or ASU, 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. ASU 2014-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016. Entities are able to use one of three prescribed transition methods. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. The Company has not yet selected a transition method as the Company is currently evaluating the impact of the amended revenue recognition guidance on its consolidated financial statements.

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 fiscal years ending after December 15, 2016. The Company does not anticipate that the adoption of ASU 2014-15 will have a material impact on its 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 the Company on January 1, 2019, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

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 the Company on January 1, 2017, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements.

3. Fair Value Measurements

Instruments Recorded at Fair Value on a Recurring Basis

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

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 and June 30, 2016 are as follows (in thousands):

		Fair value measurements at reporting date using		
	Balance as of December 31, 2015	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

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

	Balance as of June 30, 2016	Fair value measurements at reporting date using: Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash and cash equivalents:				
Money market funds(1) ...	$ 2,935	$ 2,935	$ —	$ —
U.S. Treasury bonds(1)	1,500	1,500	—	—
Short-term investments:				
U.S. Treasury bonds(2)	13,953	13,953	—	—
Total assets	$18,388	$18,388	$ —	$ —
Liabilities:				
Warrant liability	$ 213	$ —	$ —	$ 213
Total liabilities	$ 213	$ —	$ —	$ 213

(1) Classified as cash and cash equivalents on the condensed consolidated balance sheets.
(2) Classified as cash and cash equivalents and short-term investments on the condensed 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, 2015 and June 30, 2016.

The warrant liability is recorded at fair value using the Black-Scholes option pricing model based on the following assumptions as of December 31, 2015 and June 30, 2016:

	December 31, 2015	June 30, 2016
Assumed risk-free interest rate.....	1.28% - 2.06%	0.97% - 1.72%
Assumed volatility.....	66.76% - 70.66%	55.53% - 63.22%
Expected life	3.15 - 8.75 yrs	2.65 - 8.25 yrs
Expected dividend yield.....	—%	—%
Preferred stock fair value:		
Series D.....	$8.41	$6.09
Series C-1.....	$2.24	$4.64
Series C.....	$1.72	$3.48

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.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

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

Preferred stock fair value — Given the absence of a public trading market, 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 initial public offering or a merger or acquisition of the Company, given prevailing market conditions.

As of December 31, 2015 and June 30, 2016, reasonable changes in the unobservable inputs would not be expected to have a significant impact on the consolidated financial statements. The Company's policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no significant transfers into or out of Level 1, 2, or 3 for the year ended December 31, 2015 and the six months ended June 30, 2016.

The following table provides reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) for the year ended December 31, 2015 and six months ended June 30, 2016 (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
Change in fair value of warrant liability	34
Balance at December 31, 2015	332
Change in fair value of warrant liability	(119)
Balance at June 30, 2016	$ 213

Instruments Not Recorded at Fair Value on a Recurring Basis

The estimated fair value of long-term debt 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 debt approximates the current fair value because of its relatively short maturity date.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

4. Net Loss per Share and Pro Forma 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 for shares and per share data):

	Six months ended June 30,	
	2015	2016
Net loss	$ (7,157)	$ (7,712)
Weighted-average shares used in computing net loss per share	572,195	576,757
Net loss per share, basic and diluted	$ (12.51)	$ (13.37)

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):

	Six months ended June 30,	
	2015	2016
Convertible preferred stock, on an if-converted basis	8,443,994	9,102,237
Stock options to purchase common stock	—	291,690
Total	8,443,994	9,393,927

The following table summarizes our pro forma net loss per share (in thousands, except shares and per share data):

	Six months ended June 30, 2016
Numerator:	
Net loss	$ (7,712)
Change on fair value of convertible preferred stock warrants	(119)
Pro forma net loss	$ (7,831)
Denominator:	
Weighted-average shares used in computing net loss per share, basic and diluted	576,757
Pro forma adjustments to reflect assumed conversion of convertible preferred stock	9,102,237
Pro forma adjustments to reflect assumed conversion of convertible preferred stock warrants	12,217
Weighted-average shares used in computing pro forma net loss per share, basic and diluted	9,691,211
Pro forma net loss per share, basic and diluted	$ (0.81)

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

5. Balance Sheet Details

Short-term investments consist of the following at December 31, 2015 and June 30, 2016 (in thousands):

	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

	Maturity (in years)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
At June 30, 2016:					
U.S. Treasury	1 year or less	$ 13,954	$ —	$ (1)	$ 13,953

Inventory consist of the following (in thousands):

	December 31, 2015	June 30, 2016
Raw materials	$ 235	$ 407
Work in process	121	64
Finished goods	7	6
Total	$ 363	$ 477

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

	December 31, 2015	June 30, 2016
Prepaid assets	$ 234	$ 181
Interest receivable	25	34
Other assets	14	—
Total	$ 273	$ 215

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

	December 31, 2015	June 30, 2016
Computer equipment	$ 255	$ 272
Leasehold improvements	181	181
Furniture and fixtures	82	82
Scientific equipment	770	827
Construction in progress, or CIP	24	134
	1,312	1,496
Less: accumulated depreciation and amortization	(894)	(984)
Total	$ 418	$ 512

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

Depreciation and amortization expense was $0.1 million for both the six months ended June 30, 2015 and 2016.

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

	December 31, 2015	June 30, 2016
Accrued legal	$162	$248
Accrued professional fees	195	152
Accrued interest	44	44
Other accrued expenses	92	142
Total	$493	$586

6. Term Loan

In June 2013, the Company entered into a loan and security agreement, or 2013 Loan Agreement, with Square 1 Bank allowing for borrowings up to $3.0 million. In addition to the interest payments, Square 1 Bank received warrants for the purchase of up to 8,693 shares of the Company's Series C-1 convertible preferred stock. In October 2014, the Company amended the 2013 Loan Agreement and executed a $10.0 million credit facility with Square 1 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 Square 1 Bank additional warrants to purchase up to 27,869 shares of its Series D convertible preferred stock at $7.5351 per share.

The present value of the future cash flows under the 2014 Loan Agreement terms described below 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 are amortized to interest expense over the remaining term of the 2014 Loan Agreement using the effective-interest method.

The interest rate under the 2014 Loan Agreement is at a variable annual rate equal to the greater of the prime rate plus 1.75% or 5.0%, and there is an interest-only period until October 31, 2016, followed by a 24-month principal and interest period. Pursuant to the 2014 Loan Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property owned by the Company. As of June 30, 2016, unpaid borrowings under the 2014 Loan Agreement totaled $10.0 million. For the six months ended June 30, 2015 and 2016, the Company recorded immaterial amounts related to the amortization of debt discount.

The 2014 Loan Agreement includes restrictions on, among other things, the Company's ability to incur additional indebtedness, change the name or location of the Company's business, merge with or acquire

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

other entities, pay dividends or make other distributions to holders of its capital stock, make certain investments, engage in transactions with its affiliates, create liens, sell assets, pay subordinated debt, and store certain inventory and equipment with third parties. The 2014 Loan Agreement also requires that, if the Company's total cash is less than $5.0 million, the Company is required to maintain all its deposits, transaction accounts and primary investment accounts with Square 1 Bank, and if the Company's total cash is greater than $5.0 million, it is required to maintain 50% of its deposits, transaction accounts and primary investment accounts with Square 1 Bank.

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

	June 30, 2016
Face value	$10,000
Less: debt issuance costs	(117)
Total	$ 9,883
Less: current portion	(3,255)
Total	$ 6,628

As of June 30, 2016, future principal payments due under the 2014 Loan agreement are as follows (in thousands):

Year ended:	
December 31, 2016	$ 833
December 31, 2017	5,000
December 31, 2018	4,167
Total future principal payments due under the 2014 Loan Agreement	$10,000

7. Stock-Based Compensation

The Company adopted an Equity Incentive Plan, or the Plan, in 2008, under which 2,988,770 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.

The fair value of stock options for employees was estimated using a Black-Scholes option pricing model with the following assumptions:

	Six months ended June 30,	
	2015	2016
Assumed risk-free interest rate	1.57%	1.49%
Assumed volatility	61.53%	53.49%
Expected option life	6.1 years	6.1 years
Expected dividend yield	— %	— %

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

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):

	Six months ended June 30,	
	2015	2016
Cost of revenue	$ 15	$ 15
Research and development	23	25
Selling, general and administrative	62	105
Total	$100	$145

Unrecognized compensation expense at June 30, 2016 was approximately $0.6 million, which is expected to be recognized over a weighted-average term of 3.2 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 six months ended June 30, 2015 and 2016.

The following table summarizes stock option transactions for the Plan for the six months ended June 30, 2016 (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	511,252	1.41		
Options exercised	(5,709)	2.03		
Options canceled	(36,721)	2.32		
Outstanding at June 30, 2016	1,767,690	$1.41	7.7	$2,467
Vested and expected to vest at June 30, 2016	1,654,113	$1.42	7.6	$2,348
Vested and exercisable at June 30, 2016	930,644	$1.57	6.2	$1,142

All options outstanding at year-end 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 six months ended June 30, 2016, no options were early exercised.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

8. Convertible Preferred Stock and Stockholders' Deficit

Convertible Preferred Stock

Convertible preferred stock consisted of the following (in thousands, except for shares):

	As of June 30, 2016			
	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

Outstanding Warrants

The following warrants were outstanding as of June 30, 2016:

	Shares	Weighted-average exercise price	Issuance date	Expiration date
Series C	24,224	$6.1918	Feb 24, 2012	Feb 24, 2019
Series C-1	8,693	10.36	Jun 14, 2013	Jun 14, 2023
Series D	27,869	7.5351	Oct 01, 2014	Oct 01, 2024
Series D	7,962	7.5351	Mar 15, 2015	Mar 15, 2023
Series D	16,588	7.5351	Mar 16, 2015	Mar 16, 2023
Total	85,336	$7.4408		

Series E Preferred Stock

On April 29, 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 cash proceeds of $15.8 million, gross of $0.1 million in issuance costs. 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.

The convertible preferred stock has been classified as temporary equity in the accompanying balance sheets as the shares include provisions allowing the holder to cause redemption of the shares upon certain changes in control events that are outside of the Company's control.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

Amendments to Certificate of Incorporation

On April 29, 2016, the Company amended its amended and restated certificate of incorporation to:

- increase the total number of shares authorized from 63,805,954 to 79,460,759, of which 45,000,000 are designated as common stock and 34,460,759 are designated as preferred stock;
- reduce the liquidation preference on Series D preferred stock from $15.0701 per share to $7.5351 per share;
- create three classes of preferred stock- Series E, Series D and Junior preferred stock. Holders of Series E preferred stockholder receive payment of liquidation distributions and dividends prior and in preference to holders of Series D and Junior preferred stock. Holders of Series D preferred stock receive payment of liquidation distributions and dividends prior and in preference to holders of Junior preferred stock. Liquidation distributions to holders of Junior preferred stock are made pari passu and are made in preference to any payments to the holders of common stock;
- modify the IPO price at which each share of preferred stock is automatically converted to common from $11.3025 per share to $12.44 per share (as adjusted for Recapitalizations); and
- change the automatic conversion of the preferred stock to no longer require the affirmative vote of more than 67% of the Series D convertible preferred stock, but only requiring the affirmative vote of more than 67% of the holders of then outstanding preferred stock voting together as a single class.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at June 30, 2016:

Conversion of preferred stock	10,360,419
Stock options issued and outstanding	1,767,690
Authorized for future option grants	1,056,415
Warrants outstanding	85,336
Total common stock	13,269,860

9. Income Taxes

For the six months ended June 30, 2015 and 2016, the Company did not record an income tax provision. The U.S. federal and California deferred tax assets generated from the Company's net operating losses have been fully reserved, as the Company believes it is not more likely than not the benefit will be realized.

10. Commitments and Contingencies

The Company leases facilities under a noncancelable operating lease that expires on March 31, 2017. Under the terms of the facilities lease, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

Future noncancelable minimum payment obligations under the operating lease were as follows as of June 30, 2016 (in thousands):

Year ended:	
December 31, 2016	$142
December 31, 2017	71
Total future payments due under building lease	$213

Rent expense was $0.1 million for both six months ended June 30, 2015 and 2016, respectively.

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, and will thereafter automatically renew for successive terms of 12 months, subject to certain exceptions. 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 six months ended June 30, 2016 totaled $1.8 million, which represent 100% of total revenue for the period. As of June 30, 2016, the Company had accounts receivable from Bader of $0.6 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.

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS —(Continued)

12. Subsequent Events

Stock option exercises

Subsequent to June 30, 2016, stock options for 792,295 shares of the Company's common stock were exercised for proceeds of $1.0 million.

Second amendment to loan and security agreement

On September 7, 2016, the Company entered into a Second Amendment to Loan and Security Agreement, or the Amendment, with Pacific Western Bank (as successor in interest to Square 1 Bank), which amends the existing outstanding debt agreement described in Note 6. The Amendment 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 repay the existing debt with Pacific Western Bank (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. We refer to the first tranche and the second tranche collectively 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 Amendment, 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 will only be exercisable in the event that the Company borrows all or part of the second tranche.

The Amendment also requires that, if the Company's total cash is less than $15.0 million, the Company is required to maintain all its deposits, transaction accounts and primary investment accounts with Pacific Western Bank, and if the Company's total cash is greater than $15.0 million, it is required to maintain 50% of its deposits, transaction accounts and primary investment accounts with Pacific Western Bank. In addition, should the Company draw on the second tranche and its cash balance fall below $5.0 million, the Company is required to deliver a signed term sheet to Pacific Western Bank that is reasonably acceptable to the bank for the sale of the Company's equity securities.

FDA approval

On September 8, 2016, the Company received premarket approval from the FDA to market the Obalon balloon system for temporary use to facilitate weight loss in obese adults with a 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.

Through and including , 2016 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.