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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2018

or

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

Commission File Number: 001-37897

OBALON THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(760) 795-6558
(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨	Smaller reporting company	¨
		Emerging growth company	x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financing accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

Total shares of common stock outstanding as of the close of business on October 26, 2018:

Class	**Number of Shares Outstanding**
Common Stock, $0.001 par value	23,280,439

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

	September 30, 2018	December 31, 2017
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 21,552	$ 21,108
Short-term investments	8,116	23,292
Accounts receivable, net of allowance of $538 and $239, respectively	2,775	4,223
Inventory	1,955	1,418
Other current assets	909	1,714
Total current assets	35,307	51,755
Property and equipment, net	1,572	1,346
Total assets	$ 36,879	$ 53,101
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,458	$ 1,276
Accrued compensation	2,671	4,494
Deferred revenue	301	510
Other current liabilities	2,328	1,773
Current portion of long-term loan	523	1,958
Total current liabilities	7,281	10,011
Deferred rent	46	13
Long-term loan, excluding current portion	9,399	7,964
Total long-term liabilities	9,445	7,977
Total liabilities	16,726	17,988
Commitments and contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 and 300,000,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively; 23,280,310 and 17,500,604 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	23	18
Additional paid-in capital	160,130	146,474
Accumulated other comprehensive loss	(2)	(5)
Accumulated deficit	(139,998)	(111,374)
Total stockholders' equity	20,153	35,113
Total liabilities and stockholders' equity	$ 36,879	$ 53,101

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)			
Revenue	$ 2,987	$ 2,787	$ 7,065	$ 6,222
Cost of revenue	1,418	1,314	3,919	3,127
Gross profit	1,569	1,473	3,146	3,095
Operating expenses:				
Research and development	2,368	2,798	8,359	7,958
Selling, general and administrative	5,836	7,813	23,092	19,606
Total operating expenses	8,204	10,611	31,451	27,564
Loss from operations	(6,635)	(9,138)	(28,305)	(24,469)
Interest expense, net	(70)	(21)	(164)	(110)
Other expense	(40)	(11)	(155)	(66)
Net loss	(6,745)	(9,170)	(28,624)	(24,645)
Other comprehensive (loss) income	(3)	15	3	(3)
Total comprehensive loss	$ (6,748)	$ (9,155)	$ (28,621)	$ (24,648)
Net loss per share, basic and diluted	$ (0.35)	$ (0.55)	$ (1.60)	$ (1.48)
Weighted-average common shares outstanding, basic and diluted	19,457,971	16,747,791	17,837,297	16,649,447

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
	(Unaudited)	
Operating activities:		
Net loss	$ (28,624)	$ (24,645)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	428	221
Stock-based compensation	3,610	2,102
Fair value of stock issued for legal settlement	—	1,398
Loss on disposal of fixed assets	107	—
(Accretion) amortization of investment (discount) premium, net	(20)	24
Amortization of debt discount	29	31
Change in operating assets and liabilities:		
Accounts receivable, net	1,448	(2,515)
Accounts receivable from related party	—	515
Inventory	(537)	(84)
Other current assets	805	240
Accounts payable	135	534
Accrued compensation	(1,823)	174
Deferred revenue	(209)	72
Other current and long term liabilities	634	506
Net cash used in operating activities	(24,017)	(21,427)
Investing activities:		
Purchases of short-term investments	(9,103)	(80,317)
Maturities of short-term investments	24,302	41,500
Purchase of property and equipment	(867)	(904)
Net cash provided by (used in) investing activities	14,332	(39,721)
Financing activities:		
Fees paid in connection with loan amendment	(30)	—
Proceeds from issuance of common stock, net of issuance costs	9,973	—
Proceeds from stock issued under employee stock purchase plan	148	210
Proceeds from sale of common stock upon exercise of stock options	38	46
Net cash provided by financing activities	10,129	256
Net increase (decrease) in cash and cash equivalents	444	(60,892)
Cash and cash equivalents at beginning of period	21,108	72,975
Cash and cash equivalents at end of period	$ 21,552	$ 12,083
Supplemental cash flow information:		
Interest paid	$ 473	$ 416
Unpaid issuance costs	$ 160	$ —
Property and equipment in accounts payable	$ 106	$ 126

See accompanying 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 vertically-integrated medical device company focused on developing and commercializing innovative medical devices to treat obese and overweight people. Using its patented technology, the Company has developed the Obalon® balloon system, the first and only U.S. Food and Drug Administration, or FDA, approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients.

The unaudited interim condensed consolidated financial statements include the accounts of Obalon Therapeutics, Inc., and its wholly owned subsidiary, Obalon Therapeutics, LLC, which was dissolved in 2017 and had no activity in 2017.

The accompanying unaudited interim condensed 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.

In August 2018, the Company sold 5,494,506 shares of its common stock pursuant to a securities purchase agreement (the "Purchase Agreement") for aggregate gross proceeds of $10.0 million in connection with a private placement financing transaction (the "Private Placement").

As of September 30, 2018, the Company has devoted a substantial portion of its efforts to product development, raising capital, and building infrastructure, and, since January 2017, U.S. commercialization. The Company has incurred operating losses and has experienced negative cash flows from operations since its inception. In July 2012, the Company realized initial revenue from its planned principal operations. The Company recognized total revenue of $3.0 million and $2.8 million for the three months ended September 30, 2018 and 2017, respectively, and $7.1 million and $6.2 million for the nine months ended September 30, 2018 and 2017, respectively. However, the Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and has funded its activities to date almost exclusively from equity and debt financings.

Liquidity

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 September 30, 2018, its accumulated deficit was $140.0 million. Since inception, the Company has financed its operations primarily through private placements of preferred securities, the sale of common stock through its initial public offering (IPO), and a subsequent private placement, and, to a lesser extent, debt financing arrangements. The Company expects to continue to incur net losses for the foreseeable future as it continues to build its sales and marketing organization, and continues research and development efforts including clinical trials of products under development. The Company believes that its existing cash and cash equivalents, short-term investments, additional debt capacity (Note 6) and expected revenues will be sufficient to meet its capital requirements and fund its operations through for at least twelve months from the filing date of this Form 10-Q. The Company plans to seek additional debt or equity financing in order to maintain its current operating plan. Adequate funding may not be available on acceptable terms, or at all. The failure to obtain sufficient funds on acceptable terms and in a timely manner could require the Company to make significant spending reductions in its operating plan, which could delay or stop commercialization and development efforts and would have a material adverse effect on its business, results of operations and financial condition.

2. Summary of Significant Accounting Policies

Except for the revenue recognition policy described below, there were no significant changes to the accounting policies during the nine months ended September 30, 2018, from the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statements" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 5, 2018.

Revenue Recognition

The Company recognizes revenue, in accordance with ASC 606, when control of its products is transferred to its customers in an amount that reflects the consideration it expects to receive in exchange for those products. The Company's revenue recognition process involves identifying the contract with a customer, determining the performance obligations in the contract,

determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue as performance obligations are satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Revenue is generated from sales of the Obalon balloon system to physicians and institutions in the United States and to a distributor in the Middle East. The Company recognizes revenue upon shipment of its product as the Company's standard contract terms dictate that control transfers to the customer upon shipment of its product. Invoicing typically occurs upon shipment and the time period between invoicing and when payment is due is not significant. Sales taxes collected are excluded from revenues. Shipping charges billed to customers are included in revenue and related shipping cost is included in cost of revenue. The Company's revenue contracts do not provide for maintenance. Commissions are considered incremental costs to obtain a contract with a customer and paid to salespeople when contracts are executed. Commissions are recognized as a selling expense when incurred as the amortization period is one year or less.

The components of the Obalon balloon system are typically packaged in a kit and shipped to the customer at the same time, satisfying the majority of performance obligations in the contact. The Company recognizes revenue for any unsatisfied, distinct performance obligations, such as undelivered components, as they are satisfied based on the standalone selling price of each performance obligation. The Company estimates the standalone selling price of each performance obligation by estimating the expected cost of satisfying that performance obligation plus an appropriate margin. When the Company enters into contracts with multiple performance obligations, such obligations are generally satisfied within a short time frame of approximately three to six months after the contract execution date. The Company does not disclose the value of the unsatisfied performance obligations within its contracts.

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

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

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

Use of Estimates

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

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

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated financial statements as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 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 September 30, 2018 and its condensed consolidated results of operations for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 30, 2018 and 2017. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The balance sheet as of December 31, 2017 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 in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 5, 2018.

Fair Value Measurements

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

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

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

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents and trade accounts receivable, which are generally not collateralized. The Company limits its exposure to credit loss by placing its cash equivalents with high credit quality financial institutions and investing in high quality short-term debt instruments. The Company's customers consist of physicians and institutions in the United States and one international distributor. The Company establishes customer credit policies related to its accounts receivable based on historical collection experiences within the various markets in which the Company operates, historical past-due amounts, and any specific information that the Company becomes aware of such as bankruptcy or liquidity issues of customers.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Single largest customer:*				
Revenue	39.4 %	28.3 %	45.4 %	13.3 %
Second largest customer:				
Revenue	27.4 %	5.0 %	18.2 %	2.2 %

	September 30, 2018	December 31, 2017
Single largest customer:*		
Accounts receivable	34.0 %	17.4 %
Second largest customer:		
Accounts receivable	24.8 %	— %

*The Company's largest customer for the three and nine months ended September 30, 2018 was its Middle East distributor. The Company recorded $0.8 million of sales with this distributor for the three and nine months ended September 30, 2017. There were no other international sales aside from sales to this distributor for the three and nine months ended September 30, 2018 and 2017.

Net Loss per Share

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

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

Recently Issued and Adopted Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In August 2015, the FASB issued Accounting Standards Update, or ASU, 2015-14, *Revenue from Contracts with Customers (ASC 606)*, which defers the effective date of ASU 2014-09 by one year. ASC 606 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. ASC 606 is based on the principle that revenue should be recognized in an amount that reflects the consideration to which a company expects to be entitled in exchange for the transfer of promised goods or services. The Company adopted ASC 606 on January 1, 2018 using the modified retrospective implementation method.

The Company noted the following in its assessment of the impact of ASC 606 on its financial statements issued prior to fiscal year 2018:

- The majority of the Company's sales contracts fall under its standard sales agreement whereby control transfers to the customer upon delivery of the product to the named common carrier at the Company's location, satisfying the performance obligations of the contract. As such, revenue is recognized upon shipment under ASC 606 in the same way that it was recognized under the previous revenue guidance. The Company's contracts did not meet the criteria under ASC 606 for revenue recognition over time.
- Customer incentives existing prior to December 31, 2017 related to discounts that were recognized as a reduction to revenue in the same period when the related revenue was recognized or situations where the Company deferred revenue related to undelivered elements of the contract and then recognized the revenue as the undelivered elements were delivered. The Company concluded that the revenue recognition for these customer incentives under ASC 606 was the same as under the previous revenue guidance.
- Prior to December 31, 2017, the Company presented the reserve for expected sales returns as a decrease to its accounts receivable balance. Under ASC 606, the Company accounts for expected sales returns as a refund liability and presents the reserve for sales returns as a current liability in its consolidated financial statements with a corresponding asset if the returned item is expected to be re-sold. The adoption of ASC 606 resulted in an immaterial transition adjustment related to this reserve. This reclassification did not have an impact on the results of operations. The reserve for sales returns was $0.2 million at September 30, 2018.

Overall, the cumulative effect of applying the new revenue standard to all incomplete contracts as of January 1, 2018 was not material and, therefore, did not result in an adjustment to retained earnings. There was no material difference to the consolidated financial statements for the three or nine months ended September 30, 2018 due to the adoption of ASC 606.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation, to provide clarity and reduce both 1) diversity in practice and 2) cost and complexity when applying the guidance in Topic 718 to a change in the terms or conditions of a share-based payment award. ASU 2017-09 provided guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under Topic 718. The amendments in ASU 2017-09 were effective for fiscal and interim reporting periods in fiscal years beginning after December 15, 2017. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 on January 1, 2018 and the adoption did not have a material impact on the Company's consolidated financial statements or related financial statement disclosure.

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting. This ASU expands the scope of Topic 718 to include share based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. This ASU is effective for the Company on January 1, 2019 with early adoption permitted, although no earlier than the adoption date of Topic 606. The Company elected to early adopt this ASU in the quarter ended June 30, 2018, which did not have a material impact on its financial statements.

Recently Issued Accounting Pronouncements not yet adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. Under this new guidance, at the commencement date, lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. This guidance is not applicable for leases with a term of 12 months or less. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842 (Leases)*, which provides narrow amendments to clarify how to apply certain aspects of the new lease standard. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2018, with early adoption permitted. In July 2018, the FASB issued ASU No. 2018-11, *Leases Topic (842): Targeted Improvements.* This ASU provides companies an option to apply the transition provisions of the new lease standard at its adoption date instead of at the earliest comparative period presented in its financial statements. The Company is currently evaluating the potential impact of adoption of the new lease standard and the additional transition method under ASU 2018-11 on its consolidated financial statements. The Company currently believes the most significant change will be related to the recognition of a new right-of-use asset and lease liability on the Company's consolidated balance sheet for its real estate operating lease.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. The Company does not anticipate that the adoption of ASU 2017-11 will have a material impact on its consolidated financial statements unless a transaction occurs that would need to be evaluated under this guidance at which time the Company will assess the impact of this standard.

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 September 30, 2018 and December 31, 2017 are as follows (in thousands):

		Fair value measurements at reporting date using		
	Balance as of September 30, 2018	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	$ 21,552	$ 21,552	$ —	$ —
Short-term investments:				
U.S. Treasury bonds	8,116	8,116	—	—
Total assets	$ 29,668	$ 29,668	$ —	$ —

		Fair value measurements at reporting date using		
	Balance as of December 31, 2017	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	$ 12,115	$ 12,115		
U.S. Treasury bonds	8,993	8,993		
Short-term investments:				
U.S. Treasury bonds	23,292	23,292	—	—
Total assets	$ 44,400	$ 44,400	—	—

The Company’s investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as of September 30, 2018 and December 31, 2017.

Instruments Not Recorded at Fair Value on a Recurring Basis

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

4. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (6,745)	(9,170)	(28,624)	(24,645)
Weighted-average common shares outstanding, basic and diluted	19,457,971	16,747,791	17,837,297	16,649,447
Net loss per share, basic and diluted	$ (0.35)	$ (0.55)	$ (1.60)	$ (1.48)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options to purchase common stock	259,683	873,282	424,725	904,755
Total	259,683	873,282	424,725	904,755

5. Balance Sheet Details

Short term investments consist of the following as of September 30, 2018 and December 31, 2017:

	Maturity (in years)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
At September 30, 2018:					
U.S. Treasury bonds	1 year or less	$ 8,118	$ —	$ (2)	$ 8,116

	Maturity (in years)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
At December 31, 2017:					
U.S. Treasury bonds	1 year or less	$ 23,295	$ —	$ (3)	$ 23,292

Inventory consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 1,269	$ 1,046
Work in process	190	127
Finished goods	496	245
Total	$ 1,955	$ 1,418

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

	September 30, 2018	December 31, 2017
Prepaid expenses	783	1,514
Interest receivable	5	85
Other assets	121	115
Total	$ 909	$ 1,714

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

	September 30, 2018	December 31, 2017
Computer hardware	$ 405	$ 397
Computer software	274	392
Leasehold improvements	405	238
Furniture and fixtures	171	160
Scientific equipment	1,792	1,354
Construction in progress, or CIP	351	220
	3,398	2,761
Less: accumulated depreciation	(1,826)	(1,415)
Total	$ 1,572	$ 1,346

Depreciation expense was $0.1 million for each of the three months ended September 30, 2018 and 2017, and $0.4 million and $0.2 million for each of the nine months ended September 30, 2018 and 2017, respectively.

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

	September 30, 2018	December 31, 2017
Accrued legal and professional fees	$ 346	$ 289
Accrued customer incentives	903	558
Accrued clinical trial expenses	65	—
Accrued sales and other taxes	133	167
Accrued marketing expenses	6	60
Other accrued expenses	875	699
Total	$ 2,328	$ 1,773

6. Term Loan

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

In July 2018, the Company executed the Fifth Amendment to the Loan and Security Agreement (the "Loan Amendment") with Pacific Western Bank, which increased the loan capacity to $20 million from $10 million. The loan capacity of $20 million consists of two tranches as follows: a first tranche consisting of $10.0 million funded on July 10, 2018, of which the full $10.0 million was required to be used to settle the existing debt with Pacific Western Bank on a net settlement basis (pursuant to its original terms); and a second tranche consisting of an additional $10.0 million which may be drawn at any time prior to July 9, 2019. As of September 30, 2018, the Company had $10.0 million in outstanding borrowings under the Loan Agreement. The outstanding debt has a variable annual interest rate equal to the greater of the prime rate plus 1.5% per annum, or 5%, and matures in July 2022. As the prime rate was 5.25% as of September 30, 2018, the interest rate on the debt was 6.75% as of September 30, 2018. The Loan Amendment provides for an interest-only period through July 9, 2019 followed by 36 equal monthly installments of principal and interest with the first principal payment due on August 9, 2019. The Loan Agreement may be prepaid in full at any time with no additional cost.

The loan fee paid and the remaining balance of debt issuance costs and debt discount on the previous loan agreements held with Pacific Western Bank are amortized to interest expense over the remaining term of the Loan Agreement using the effective-interest method.

The Loan Agreement also states that the Company's accounts maintained with the bank contain an aggregate balance in an amount equal to or greater than the total amount of outstanding debt under the Loan Agreement. In addition, the Company is required to deposit into such accounts a portion or all of the net proceeds from its next equity offering, which the Company satisfied in connection with the completion of the private placement in August 2018. Even if the cash in the Company's

accounts maintained with the bank falls below the total amount of outstanding debt under the Loan Agreement, the Company is not restricted from using the funds in the ordinary course of business.

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

	September 30, 2018
Face value	$ 10,000
Less: unamortized debt issuance costs	(78)
Total term loan	$ 9,922
Less: current portion of long-term loan	(523)
Total long-term loan, excluding current portion	$ 9,399

As of September 30, 2018, future principal payments due under the Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2018	$ —
December 31, 2019	1,389
December 31, 2020	3,333
December 31, 2021	3,333
December 31, 2022	1,945
Total future principal payments due under the Loan Agreement	$ 10,000

7. Stock-Based Compensation

Equity Incentive Plan

As of September 30, 2018, 892,827 stock options and awards remained available for future grant under the 2016 Equity Incentive Plan. No other plans had options or awards available for grant.

The Company recorded stock-based compensation in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of revenue	$ 28	$ 30	68	83
Research and development	307	118	859	315
Selling, general and administrative	672	875	2,683	1,704
Total	$ 1,007	$ 1,023	$ 3,610	$ 2,102

Unrecognized compensation expense at September 30, 2018 was approximately $6.6 million, which is expected to be recognized over a weighted-average term of 2.0 years.

Incentive Stock Options

The following table summarizes stock option transactions for the 2016 Equity Incentive Plan for the nine months ended September 30, 2018 (in thousands, except shares and per share data):

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2017	2,979,285	$ 6.49		
Options granted	1,565,864	4.92		
Options exercised	(26,003)	1.46		
Options canceled	(957,238)	6.32		
Outstanding at September 30, 2018	3,561,908	$ 5.88	7.8	$ 1,194
Vested and expected to vest at September 30, 2018	3,327,958	$ 5.85	7.8	$ 1,168
Vested and exercisable at September 30, 2018	1,662,409	$ 5.93	6.6	$ 845

Restricted Stock Awards

The following table summarizes restricted stock award transactions for the 2016 Equity Incentive Plan for the nine months ended September 30, 2018:

	Number of awards	Weighted-average grant date fair value
Outstanding at December 31, 2017	413,000	$ 9.98
Awards granted	425,942	4.10
Awards vested	—	—
Awards canceled	(212,000)	10.00
Outstanding at September 30, 2018	626,942	$ 5.99

8. Stockholder's Equity

In August 2018, the Company sold 5,494,506 shares of its common stock pursuant to the Purchase Agreement for aggregate gross proceeds of $10.0 million in connection with the private placement. Investors in the private placement included certain unaffiliated investors, members of the Company's management team and the board of directors and certain of their affiliated funds, including Domain Associates and InterWest Partners.

The Company incurred $0.2 million, including an immaterial amount paid as of September 30, 2018, of legal, accounting, registration and other professional fees related to the private placement. These amounts were charged against additional paid-in capital upon completion of the private placement.

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

Outstanding Warrants

The following equity classified warrants were outstanding as of September 30, 2018:

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

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following as of September 30, 2018:

Stock options issued and outstanding	3,561,908
Authorized for future option and ongoing vesting of award grants	892,827
Authorized for future issuance under ESPP	476,259
Warrants outstanding	24,224
Total	4,955,218

9. Income Taxes

For the three and nine months ended September 30, 2018 and 2017, 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 more likely than not the benefit will not be realized.

10. Commitments and Contingencies

Leases

On June 1, 2018, the Company amended its office lease agreement for the purpose of extending the term of the current lease on its corporate headquarters and leasing an additional 2,700 square feet of space in an adjacent building.

The Company leases facilities under a noncancelable operating lease that expires on March 31, 2022. Under the terms of the facilities lease, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs.

Future noncancelable minimum payment obligations under the operating lease were as follows as of September 30, 2018 (in thousands):

Year ended:		
December 31, 2018	$	117
December 31, 2019		474
December 31, 2020		487
December 31, 2021		501
December 31, 2022		126
Total future payments due under building lease	$	1,705

Termination of Stock Offering

On January 23, 2018, the Company issued a press release announcing the termination of its previously announced offering of common stock due to a purported whistleblower compliant, which was later found to be without merit. As of September 30, 2018, the Company did not record any liability associated with termination of the offering, and management believed that the likelihood is remote that the Company will incur material fees in the future.

Shareholder Lawsuit

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against the Company and certain of its executive officers in the United States District Court for the Southern District of California (Hustig v. Obalon Therapeutics, Inc., et al., Case No. 3:18-cv-00352-AJB-WVG, and Cook v. Obalon Therapeutics, Inc. et al., Case No. 3:18-cv-00407-CAB-RBB). On July 24, 2018, the court appointed Inter-Local Pension Fund GCC/IBT as lead plaintiff. On October 5, 2018, plaintiffs filed an amended complaint. The amended complaint alleges that the Company and certain of its executive officers made false and misleading statements and failed to disclose material adverse facts about its business, operations, and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of the Company's initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The case is at a preliminary stage and the Company intends to vigorously defend against it.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Quarterly Report on Form 10-Q. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, timing and results of preclinical and clinical development activities, and potential regulatory approval and commercialization of products and product candidates. In some cases, forward looking-statements may be identified by terminology such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek" and similar expressions and variations thereof. These words are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, research and development, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee 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 report to conform these statements to actual results or to changes in our expectations, except as required by law.

As used in this Quarterly Report on Form 10-Q, the terms "Obalon," "the Company," "we," "us," and "our" refer to Obalon Therapeutics, Inc. and, where appropriate, its consolidated subsidiary, unless the context indicates otherwise.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2017, included in our Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 5, 2018.

OVERVIEW

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

In September 2016, we received premarket approval, or PMA, from the FDA, and commenced U.S. commercialization in January 2017 through a direct sales force. The Obalon balloon system is FDA approved for temporary use to facilitate weight loss in obese adults with a body mass index, or BMI, of 30 to 40, or approximately 30 to 100 pounds overweight, 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.

In November 2017, we submitted a PMA supplement to the FDA for our Obalon Touch™ Inflation System, also known as Obalon Touch. The Obalon Touch is our next generation inflation system that is designed to be automated, easier to operate and to provide more reliable and consistent Obalon balloon placement. In September 2018, we received approval of a PMA

supplement from the FDA for our Obalon Touch Inflation System. At this time, we intend to commercialize the Obalon Touch only in combination with the Obalon Navigation System, if approved.

We are selling the Obalon balloon system on a self-pay, non-reimbursed basis into existing physician specialty areas with weight loss practices, such as bariatric surgeons and gastroenterologists. In addition, we are selling to plastic surgeons, due to their client base and experience managing self-pay practices. Physicians can market our product as a highly differentiated, non-surgical weight loss procedure. We are also selling to retail medical groups that have experience with cash-pay surgical and non-surgical products and procedures. Based on our product design and commercial data, we believe the Obalon balloon system provides potentially attractive economics for patients and physicians. We expect to continue to focus our sales and marketing efforts primarily on selling our product in the United States through a direct sales force. We have recently revised the field sales team structure to support our customers more efficiently. Our updated field structure includes a business development manager, corporate account director, health systems development manager and product specialists.

We intend to drive patient awareness and interest in part through multiple efforts that may include digital, offline and social marketing, as well as public relations efforts targeted to obtain online and offline media coverage. We estimate that there were more than 30 million views of our digital advertisements and more than five million views of our digital videos in 2017, with more views of each occurring in both the third quarter and fourth quarter of 2017 than in the first half of 2017. We also estimate that there were more than 15 million views of our digital advertisements and more than 2.5 million views of our videos in the first quarter of 2018 alone. We estimate that there were over one million unique visits to our website in 2017, and over 400,000 searches on our website for physicians capable of placing our Obalon balloon system in 2017. During the nine months ended September 30, 2018, we estimate that there were over 1.4 million unique visits to our website and over 500,000 searches on our website for physicians capable of placing our Obalon balloon system. We also generated over 46,000 patient leads to our physician partners in the United States during 2017 and over 44,000 leads for the nine months ended September 30, 2018.

Intragastric balloons represent a relatively new category of treatment for weight loss in the United States and the current market is small and immature. Our strategy is to methodically build the foundation to establish the Obalon balloon system as an important, growing and sustainable treatment for weight loss. We are currently employing a focused launch strategy to ensure our initial target accounts achieve clinical and economic success before launching more broadly in the U.S. and international markets. We expect to continue investing in various activities to develop the intragastric balloon market for the foreseeable future.

We generated total revenue of $3.0 million and $2.8 million for the three months ended September 30, 2018 and 2017, respectively, and $7.1 million and $6.2 million for the nine months ended September 30, 2018 and 2017, respectively. For the three months ended September 30, 2018 and 2017, our net loss was $6.7 million and $9.2 million, respectively, and for the nine months ended September 30, 2018 and 2017, our net loss was $28.6 million and $24.6 million, respectively. We have not been profitable since inception, and as of September 30, 2018, our accumulated deficit was $140.0 million. From inception through September 30, 2018, we have financed our operations primarily through private placements of our preferred securities, the sale of common stock in our initial public offering, or IPO, in October 2016, and a subsequent private placement, and, to a lesser extent, debt financing arrangements.

In January 2018, we issued a press release announcing the termination of a previously announced offering of common stock and the underwriting agreement relating to the offering. The termination was due to a purported whistleblower complaint alleging improper revenue recognition during the fourth quarter of 2017. Our audit committee led an investigation utilizing outside counsel and a forensic accounting firm, and concluded that the allegations in the complaint were without merit. However, the negative publicity, distraction and monetary cost caused by the allegations and the subsequent investigation has had and may continue to have a negative impact on our organization, our revenue, our results of operations and our ability to secure additional financing. In August 2018, we sold 5,494,506 shares of common stock in a private placement pursuant to a securities purchase agreement for aggregate gross proceeds of $10.0 million.

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

COMPONENTS OF OUR RESULTS OF OPERATIONS

Revenue

Revenue reflects sales of our Obalon balloon system directly to physicians and institutions in the United States and sales of our Obalon balloon system to our Middle East distributor.

Prior to December 31, 2016, all of our sales were outside the United States. In January 2017, we shifted our focus to commercialization efforts in the United States and recognized our initial U.S. revenue. We will continue to focus on selling our Obalon balloon system in the United States, which we anticipate 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, to date we have experienced limited penetration of the U.S. market, and the degree to which our revenue will increase depends on many factors, including our ability to develop the currently small and immature intragastric balloon market, acceptance of our current Obalon balloon system and future generations by doctors and patients, our ability to scale production in a cost effective manner, the emergence of competing products, actions by regulatory bodies and general economic trends. The amount of and timing of revenue recognition may also be impacted by the customer incentive programs we decide to offer.

Cost of revenue and gross margin

Cost of revenue consists primarily of costs related to the direct materials and direct labor that are used to manufacture our products and the overhead costs that directly support manufacturing. Currently, a significant portion of our cost of revenue consists of manufacturing overhead, which is mostly fixed in nature. These overhead costs include the costs of compensation for operations management, engineering support, material procurement and inventory control personnel, outside consultants, production related supplies, allocated quality assurance and facilities costs, and depreciation on production equipment. We expect cost of revenue to increase in absolute dollars to the extent our total revenue grows but decrease as a percentage of total of revenue over time as the fixed portion of our overhead costs is allocated over a greater number of units produced.

We calculate gross margin as gross profit divided by total revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, geographic mix, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to increase over the long term as our production volume increases, U.S. sales mix increases as a percentage of total sales and as we allocate the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby reducing our per unit manufacturing costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs per unit and increase our gross margin. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter as we adopt new manufacturing processes and technologies, continue to introduce new products, expand manufacturing capacity when required, discontinue obsolete products and enter international markets. As we have scaled manufacturing, we have experienced challenges in our ability to meet commercial demand. While we have taken steps to address these challenges, we cannot assure you those steps will be sufficient or that additional challenges will not arise as we continue with the commercialization of our Obalon balloon system.

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

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, commissions, benefits, travel expense and stock-based compensation expense. Other SG&A expenses include promotional and advertising activities, marketing, conferences and trade shows, professional services fees, including legal fees, accounting fees, insurance costs, general corporate expenses, and allocated facilities-related expenses. SG&A expenses are expected to increase in absolute dollars and may vary as a percentage of total revenue for the foreseeable future as we continue to expand our sales and marketing infrastructure to drive and support anticipated growth in revenue.

RESULTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Condensed consolidated statements of operations data:				
Revenue	$ 2,987	$ 2,787	$ 7,065	$ 6,222
Cost of revenue	1,418	1,314	3,919	3,127
Gross profit	1,569	1,473	3,146	3,095
Operating expenses:				
Research and development	2,368	2,798	8,359	7,958
Selling, general and administrative	5,836	7,813	23,092	19,606
Total operating expenses	8,204	10,611	31,451	27,564
Loss from operations	(6,635)	(9,138)	(28,305)	(24,469)
Interest expense, net	(70)	(21)	(164)	(110)
Other expense,	(40)	(11)	(155)	(66)
Net loss	(6,745)	(9,170)	(28,624)	(24,645)
Other comprehensive (loss) income	(3)	15	3	(3)
Net loss and comprehensive loss	$ (6,748)	$ (9,155)	$ (28,621)	$ (24,648)

Comparison of three months ended September 30, 2018 and 2017

Total revenue. Total revenue increased $0.2 million to $3.0 million during the three months ended September 30, 2018, compared to $2.8 million during the three months ended September 30, 2017. The revenue increase was due primarily to an increase of $0.4 million in sales to our Middle East distributor, partially offset by a decrease of $0.2 million in U.S. sales. Overall unit sales increased year over year due to larger shipments to our Middle East distributor, which is sold at a lower average transfer price and which lowered the worldwide average selling price. U.S. sales decreased despite an increase in sales to a single customer of approximately $0.7 million. Going forward, we believe sales to this customer, which was our second largest customer for the quarter, could decrease as the customer has indicated an intention to reduce or discontinue future purchases of our products.

Cost of revenue and gross profit. Cost of revenue increased $0.1 million during the three months ended September 30, 2018, compared with three months ended September 30, 2017. This was primarily attributable to an increase in overhead costs associated with manufacturing and an increase in costs of materials associated with higher volume sold. Gross profit as a percentage of revenue remained consistent at 53% during the three months ended September 30, 2018 and 2017.

Research and development expenses. R&D expenses decreased $0.4 million to $2.4 million during the three months ended September 30, 2018, compared to $2.8 million during the three months ended September 30, 2017. This decrease was due primarily to decreases in supplies and outside processing expense of $0.5 million, as the third quarter of 2017 had higher costs associated with the development for the Obalon Navigation System and the Obalon Touch Inflation System.

Selling, general and administrative expenses. SG&A expenses decreased $2.0 million to $5.8 million during the three months ended September 30, 2018, compared to $7.8 million during the three months ended September 30, 2017. The change from the prior period was primarily driven by a $1.4 million non-cash expense related to the fair value of shares of our common stock issued in a settlement of a previously outstanding patent litigation case with Polyzen during the third quarter of 2017. The

remaining decrease relates primarily to lower spending on marketing and advertising programs, sales commissions, and stock compensation expense.

Interest expense, net. Interest expense, net was immaterial during the three months ended September 30, 2018 and 2017.

Comparison of nine months ended September 30, 2018 and 2017

Total revenue. Total revenue increased $0.9 million to $7.1 million during the nine months ended September 30, 2018, compared to $6.2 million during the nine months ended September 30, 2017. This increase was primarily due to a $2.4 million increase in sales to our Middle East distributor, partially offset by a $1.5 million decrease in U.S. revenues. The period over period increase resulted from an increase in balloon units sold that was primarily attributable to the initiation of commercialization of the six-month balloon to our Middle East distributor which began in the third quarter of 2017. This increase was partially offset by lower balloon units sold in the United States, coupled with a lower average selling price. U.S. sales decreased despite an increase in sales to a single customer of approximately $1.1 million. Going forward, we believe sales to this customer, which was our second largest customer for the nine month period, could decrease as the customer has indicated an intention to reduce or discontinue future purchases of our products.

Cost of revenue and gross profit. Cost of revenue increased $0.8 million to $3.9 million during the nine months ended September 30, 2018, compared to $3.1 million during the nine months ended September 30, 2017. This increase was primarily attributable to an increase in overhead costs associated with manufacturing, payroll related expenses, and an increase in materials costs associated with higher volume sold. Gross profit remained consistent at $3.1 million during the nine months ended September 30, 2018 and nine months ended September 30, 2017. Gross profit as a percentage of revenue decreased to 45% during the nine months ended September 30, 2018, compared to 50% during the nine months ended September 30, 2017. This was primarily attributable to geographic mix as sales to our Middle East distributor are sold at a lower average selling transfer price.

Research and development expenses. R&D expenses increased $0.4 million to $8.4 million during the nine months ended September 30, 2018, compared to $8.0 million during the nine months ended September 30, 2017. This increase was due primarily to increases in stock compensation expense of $0.5 million and clinical trial expense of $0.3 million for our next generation products, including the Obalon Navigation System and Obalon Touch Inflation System. The increase was partially offset by decreases in supplies and outside processing expense.

Selling, general and administrative expenses. SG&A expenses increased $3.5 million to $23.1 million during the nine months ended September 30, 2018, compared to $19.6 million during the nine months ended September 30, 2017. This was attributable to a $1.3 million increase in legal, accounting fees and other charges incurred relating to the investigation by our audit committee utilizing outside counsel and a forensic accounting firm over whistleblower allegations made in early 2018, a $1.0 million increase in spending on marketing and advertising programs, and a $1.0 million increase in stock-based compensation. The remaining increase related primarily to payroll expenses of $1.7 million due to an increase in headcount, sales and marketing consultants and travel related expenses. This increase was partially offset by the impact of a $1.4 million non-cash expense related to the fair value of shares of our common stock issued in a settlement of a previously outstanding patent litigation case with Polyzen during the third quarter of 2017 for which there was no similar expense in the third quarter of 2018.

Interest expense, net. Interest expense, net increased $0.1 million to $0.2 million during the nine months ended September 30, 2018, compared to $0.1 million during the nine months ended September 30, 2017. The increase was attributable to the increase in the prime rate during the nine months ended September 30, 2018 compared to the prior year period.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2018, we had cash, cash equivalents and short-term investments of $29.7 million and an accumulated deficit of $140.0 million. Our primary sources of capital have been private placements of preferred stock, the sale of common stock in our IPO, and a subsequent private placement, and, to a lesser extent, the incurrence of debt. As of September 30, 2018, we had $10.0 million in debt outstanding with Pacific Western Bank (as successor in interest to Square 1 Bank), with the ability to borrow an additional $10.0 million available until July 9, 2019.

In August 2018, we closed a private placement and received aggregate gross proceeds of $10.0 million from the sale of 5,494,506 shares of common stock.

We expect to incur substantial expenditures in the next twelve months to continue developing the immature intragastric balloon market, support the U.S. commercialization of our product and to support continued research and development. In particular, we expect our costs and expenses to increase in the future as we continue (i) U.S. commercialization of our product, including the costs associated with a direct sales force, the expansion of our manufacturing capacity, and efforts to develop the immature intragastric balloon market and (ii) research and development, including conducting clinical trials of our products in development. Additionally, we expect to continue to incur substantial costs as a result of operating as a public company. We plan to seek additional debt or equity financing in order to maintain our current operating plan. Adequate funding may not be available to us on acceptable terms, or at all. The failure to obtain sufficient funds on acceptable terms or in a timely manner could force us to make significant spending reductions in our operating plan, which could delay or stop some of our commercialization and development efforts and would have a material adverse effect on our business, results of operations and financial condition. We believe that our existing cash and cash equivalents, additional debt capacity and expected revenues will be sufficient to meet our capital requirements and fund our operations through twelve months from the date of this filing; however our future capital requirements will depend on many factors, including:

- the costs and expenses of maintaining and growing our U.S. sales and marketing infrastructure and our manufacturing operations;
- the costs and results of our efforts to develop the immature intragastric balloon market;
- 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 or other international markets;
- the quality of our products in clinical and commercial use;
- 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 and patients;
- the number and types of future products we develop and commercialize;
- our ability to scale our manufacturing operations to meet demand;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Additional financing, if necessary, may not be available on a timely basis on terms acceptable to us, or at all. We may raise funds in equity or debt financings or enter into additional credit facilities in order to access funds for our capital needs. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment or expansion of sales and marketing capabilities or other activities necessary to commercialize our products.

Loan and security agreement

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

In July 2018, we executed the Fifth Amendment to the Loan and Security Agreement (the "Loan Amendment") with Pacific Western Bank, which increased the loan capacity to $20 million from $10 million. The loan capacity of $20 million consists of two tranches as follows: a first tranche consisting of $10.0 million funded on July 10, 2018, of which the full $10.0 million was required to be used to settle the existing debt with Pacific Western Bank on a net settlement basis (pursuant to its original

terms); and a second tranche consisting of an additional $10.0 million which may be drawn at any time prior to July 9, 2019. As of September 30, 2018, we had $10.0 million in outstanding borrowings under the loan and security agreement. The outstanding debt has a variable annual interest rate equal to the greater of the prime rate plus 1.5% per annum, or 5%, and matures in July 2022. As the prime rate was 5.25% as of September 30, 2018, the interest rate on the debt was 6.75% as of September 30, 2018. The Loan Amendment provides for an interest-only period through July 9, 2019 followed by 36 equal monthly installments of principal and interest with the first principal payment due on August 9, 2019. Pursuant to the loan and security agreement, we provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property, owned by us.

The loan and security agreement provides for restrictions on, among other things, our ability to incur additional indebtedness, change the name or location of our business, change our business, merge with or acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with our affiliates, create liens, sell assets, pay any subordinated debt, and store certain inventory and equipment with third parties. In addition, the loan and security agreement requires that our accounts maintained with the bank contain an aggregate balance in an amount equal to or greater than the total amount of outstanding debt under the loan and security agreement. We are also required to deposit into such accounts a portion or all of the net proceeds from our next equity offering, which we satisfied in connection with the completion of the private placement in August 2018. Even if the cash in our accounts maintained with the bank falls below the total amount of outstanding debt under the Loan Agreement, we are not restricted from using the funds in the ordinary course of business.

CASH FLOWS

	Nine Months Ended September 30,	
	2018	**2017**
Net cash (used in) provided by:		
Operating activities	(24,017)	(21,427)
Investing activities	14,332	(39,721)
Financing activities	10,129	256
Net increase (decrease) in cash and cash equivalents	444	(60,892)

Net cash used in operating activities

During the nine months ended September 30, 2018, net cash used in operating activities was $24.0 million, consisting primarily of a net loss of $28.6 million, offset by a decrease in net operating assets of $0.5 million primarily related to a decrease in accounts receivable and prepaid other current assets, offset by the decrease in accrued compensation. These items were further offset by non-cash charges of $4.2 million, consisting primarily of stock-based compensation expense and depreciation expense.

During the nine months ended September 30, 2017, net cash used in operating activities was $21.4 million, consisting primarily of a net loss of $24.6 million, and an increase in net operating assets of $0.5 million related to an increase in accounts receivable offset by an increase in accounts payable and accrued liabilities. This increase in net operating assets was further offset by non-cash charges of $3.8 million, consisting of primarily stock-based compensation expense, non-cash expense related to the settlement of the Polyzen case, and depreciation expense.

Net cash provided by (used in) investing activities

During the nine months ended September 30, 2018, net cash provided by investing activities was $14.3 million, consisting primarily of maturities of short-term investments, slightly offset by purchases of short-term investments and capital expenditures.

During the nine months ended September 30, 2017, net cash used in investing activities was $39.7 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 nine months ended September 30, 2018, net cash provided by financing activities was $10.1 million, consisting primarily of proceeds from issuance of common stock, net of issuance costs of $10.0 million and proceeds from purchases of common stock pursuant to our Employee Stock Purchase Plan.

During the nine months ended September 30, 2017, net cash provided by financing activities was $0.3 million, consisting primarily of proceeds received from purchases of common stock pursuant to our Employee Stock Purchase Plan.

OFF-BALANCE SHEET ARRANGEMENTS

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. 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. We believe that the accounting policies related to revenue recognition, accrued research and development costs, stock-based compensation expense and income taxes are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Aside from newly implemented accounting policies relating to the implementation of ASC 606, as discussed in Note 2 to our Unaudited Interim Condensed Consolidated Financial Statements under the heading "Revenue Recognition," there have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Operations included in the Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 5, 2018.

RECENT ACCOUNTING PRONOUNCEMENTS

Except as described in Note 2 to our Unaudited Interim Condensed Consolidated Financial Statements under the heading "Recent Accounting Pronouncements" and the recent adoption of the new revenue recognition guidance found in ASC 606, there have been no new accounting pronouncements or changes to accounting pronouncements during the nine months ended September 30, 2018, as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 5, 2018.

JOBS ACT ACCOUNTING ELECTION

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

ITEM 3. 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 September 30, 2018, our aggregate outstanding indebtedness was $10.0 million, which bears interest at the rate equal to the greater of the prime rate plus 1.50% or 5.0%. We do not believe an immediate 10% increase in interest rates would have a material effect on interest expense for the loan with Pacific Western Bank, and therefore we do not expect our operating results or cash flows to be materially affected to any degree by a sudden change in market interest rates.

CREDIT RISK

As of September 30, 2018, our cash and cash equivalents were maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of these institutions and believe they have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

EFFECTS OF INFLATION

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

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

ITEM 1A. 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 Quarterly Report on Form 10-Q, including our unaudited interim condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. The market price of our common stock would likely decline, and you could lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS

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. In the second half of 2016, we significantly expanded our U.S. sales and marketing organization. Before launching our current generation Obalon balloon system in the United States in January 2017, we sold a previous generation of our product in certain international markets. Our commercial sales experience has been limited. We have incurred significant losses in each period since our inception in 2008, with net losses of $6.7 million and $9.2 million during the three months ended September 30, 2018 and 2017, respectively, and $28.6 million and $24.6 million during the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of approximately $140.0 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop, seek and obtain regulatory approval for our current and future generation Obalon balloon system, sell our Obalon balloon system in international markets, and commercialize our Obalon balloon system in the United States.

We expect our costs and expenses to increase in the future as we continue U.S. commercialization of our product, including the cost of a direct sales force and associated marketing support, investment to develop the immature intragastric balloon market, and the expansion of our manufacturing capacity. We will also continue to expend substantial amounts on research and development of new products, including conducting clinical trials of our products currently in development. In addition, as a public company, we incur significant legal, accounting, insurance, compliance and other expenses that we would not incur as a private company. As a result, we expect our losses to continue for the foreseeable future. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

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

We were incorporated in 2008, and to date our business activities have been focused on the development and regulatory approval of our Obalon balloon system and building the commercial infrastructure to sell our product in the United States. 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 and accessories. Through 2016, our primary commercial sales experience was limited to sales to distributors in a limited number of countries outside the United States. In January 2017, we began selling our Obalon 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 and 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 and the rate at which patients seek treatment from physicians;
- changes in the composition of our customer base caused by acquisition of private medical practices by large hospitals could extend our selling cycle;
- positive or negative media coverage, or public, patient and/or physician perception, of our Obalon balloon system, the procedures or products of our competitors, or our industry;
- any safety or efficacy concerns that arise through physician and patient experience with our Obalon balloon system;
- any safety or efficacy concerns for the category of intragastric balloons, including liquid-filled balloons, as the FDA has issued three Health Care Provider warning letters specific to liquid-filled intragastric balloons citing potential risks, including death;
- our ability to develop, obtain regulatory approval for, and successfully launch our next generation products and the success of our next generation products in the marketplace;
- our ability to maintain our current or obtain further regulatory clearances or approvals;
- delays in, or failure of, product and component deliveries by our third-party suppliers;
- difficulties in producing a sufficient quantity of our product to meet commercial demand due to shortages of component parts or due to issues in the manufacturing process;
- introduction of new procedures or products for treating obese or overweight patients that compete with our product;
- adverse changes in the economy that reduce patient demand for elective procedures;
- performance of our international distributors; and
- favorable or unfavorable positions developed on intragastric balloons, or the Obalon balloon system by professional medical associations, such as the American Society for Metabolic and Bariatric Surgery (ASMBS), the American Society for Gastrointestinal Endoscopy (ASGE), or other organizations with influence on physicians.

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

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

We 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 expect to continue to invest in the future, including the expansion of our direct sales force, investment in marketing programs, the expansion of our manufacturing facilities and as we continue to spend on research and development, including conducting clinical trials of our products in development and completing development and commercialization of advancements to our existing Obalon balloon system as well as our additional products under development. Additionally, we will continue to incur additional general and administrative costs as a result of supporting growth and operating as a public company. We plan to seek additional debt or equity financing in order to maintain our current operating plan. Adequate funding may not be available to us on acceptable terms, or at all. The failure to obtain sufficient funds on acceptable terms or in a timely manner could force us to make significant spending reductions in our operating plan, which could delay or stop some of our commercialization and development efforts and would have a material adverse effect on our business, results of operations and financial condition. We

believe that our existing cash and cash equivalents, additional debt capacity, and expected revenues will be sufficient to meet our capital requirements and fund our operations through twelve months from the date of this filing; however our future capital requirements will depend on many factors, including:

- the rate at which the currently small and immature intragastric balloon market develops;
- our ability to scale manufacturing in a cost-effective manner to meet demand;
- the costs and expenses of our U.S. sales and marketing infrastructure and our manufacturing operations;
- the degree of success we experience in commercializing our Obalon balloon system;
- the revenue and gross profit generated by sales of our Obalon balloon system and any other products that may be approved in the United States;
- the degree of success we experience in retaining and expanding international sales of our Obalon balloon system;
- 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 generation products we develop and commercialize and their success and adoption in the marketplace;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- costs of operating as a public company and compliance with existing and future regulations; and
- the extent and scope of our general and administrative expenses.

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

In January 2018, we issued a press release announcing the termination of a previously announced offering of common stock and the underwriting agreement relating to the offering. The termination was due to a purported whistleblower complaint alleging improper revenue recognition during the fourth fiscal quarter of 2017. Our audit committee led an investigation utilizing outside counsel and a forensic accounting firm, and concluded that the allegations in the complaint were without merit. However, the negative publicity, distraction and monetary cost caused by the allegations and the subsequent investigation has had and may continue to have a negative impact on our organization, our revenues, our results of operations and our ability to secure additional financing.

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 represent a relatively new category of treatment for obese and overweight patients that is small and immature. 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. To date, we have experienced limited penetration of this market, and our success depends in large part on our ability to further develop the currently small and

immature intragastric balloon market, educate physicians and patients, and successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our Obalon balloon system. We are currently employing a focused launch strategy in select U.S. geographies to ensure our initial target accounts achieve clinical and economic success before launching more broadly in the U.S. and international markets. We expect to continue investing in the various activities to develop the intragastric balloon market for the foreseeable future. Since we received PMA approval for the Obalon balloon system in September 2016, we have engaged in an active marketing campaign to raise awareness of our Obalon balloon system and its benefits among physicians and patients, 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 are targeting our sales efforts towards bariatric surgeons, gastroenterologists, and plastic surgeons, because they are either the physicians treating obese and overweight patients, have experience with endoscopic procedures and/or have experience with cash pay medical treatments. 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. Since February 2017, the FDA has issued three separate letters to healthcare providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. We are aware of the filing of additional reports of serious adverse events, including deaths, associated with liquid-filled balloons since the issuance of the FDA letters to health care providers. While the advisory letters were specific to liquid-filled intragastric balloons and not the Obalon Gas-Filled Balloon, these letters could create negative perceptions of the entire category and slow down the acceptance of the Obalon balloon system. Medical professional associations, such as ASMBS, have or may publish positions to their memberships which may be favorable or unfavorable toward the use of intragastric balloons, or the Obalon Balloon specifically. Additionally, if patients undergoing treatment with our Obalon balloon system perceive the weight loss inadequate or adverse events too numerous or severe as compared with the treatment rates of alternative balloons or procedures, it will be difficult to demonstrate the value of our Obalon balloon system to patients and physicians. As a result, demand for our Obalon balloon system may decline or may not increase at the pace or to the levels we expect.

If we 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:

- lack of access or reluctance to acquire access to ancillary equipment, such as, x-ray and endoscopy, which are necessary to place and remove the Obalon balloon system;
- 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;
- time and skill commitment that may be required to gain familiarity with a new system; and
- difficulty convincing physicians of the economic benefit of our product to their practice.

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, and our international distributor's ability, to educate and train physicians on its safe and proper use. If we or our international distributor 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 and our international distributor 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, or our international distributor are unable to provide an adequate training program, product misuse may occur that could lead to SADEs that may need to be reported to the FDA. 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 and safely. In addition, it is also critical for physicians to be educated and trained on best practices in order to achieve optimal results, including patient selection and eligibility criteria as well as complementary methods of use such as diet or behavioral modification programs. Convincing physicians to dedicate the time and resources necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. This training process may also take longer than we expect. 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. Physicians may not follow our suggested practices when treating patients with our products. 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.

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

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

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

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 pivotal trial, 7.6% of the combined treatment and control group patients failed to swallow a capsule with the microcatheter attached, despite success swallowing a placebo that did not have a catheter attached. We are experiencing similar rates in U.S. commercial usage. There have also been instances where balloon deployment was negatively impacted due to a leak in the microcatheter, caused by the patient biting the catheter during placement and requiring endoscopic removal. There may be other reasons for unsuccessful placements 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 and institutions 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, that could expose us to expensive litigation, divert management's attention and harm our reputation and business.

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

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

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

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

We have limited experience as a company in the sales and marketing of our products. Prior to 2017, the majority of our product sales had been to a single international distributor in the Middle East. We first sold our products to physicians and institutions in the United States in 2017, and we anticipate the United States to be our primary market focus going forward. Training our U.S. sales force in use of our Obalon balloon system to achieve the level of clinical competency expected by physicians, and to comply with applicable federal and state laws and regulations and our internal policies and procedures requires significant time, expense and attention. It can take several months to recruit and fully train a sales representative to be productive. Our business may be harmed if there is excessive turnover in our marketing team and sales force, or our efforts to train and retain our sales force do not generate a corresponding increase in revenues. In particular, there is significant competition for qualified and experienced sales and marketing personnel. If we are unable to hire, develop and retain talented sales and marketing personnel or if new personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenues sufficiently to offset the cost incurred.

In addition, factors that may inhibit our efforts to commercialize our Obalon balloon system 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;
- efforts by our competitors to commercialize products or procedures that address a similar patient population; and
- the existence of negative publicity about us or our products.

Our ability to increase our customer base and achieve broader market acceptance of our Obalon balloon system will depend to a significant extent on our ability to efficiently expand our marketing programs which create physician and patient demand for our product. We are dedicating significant financial and other resources to our marketing programs. Our business will be harmed if our marketing efforts and expenditures do not generate a sufficient increase in revenue to offset their cost.

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

We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA and Federal Trade Commission. For example, adverse events, product complaints, off-label usage by physicians, unapproved marketing or other unintended messages could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill.

We do not expect that physicians or patients will receive third-party reimbursement for treatment with our products. As a result, we expect that our success will depend on the ability and willingness of physicians to adopt self-pay practice management infrastructure and of patients to pay out-of-pocket for treatment with our products.

Certain elective treatments, such as an intragastric balloon, are typically not covered by insurance. Accordingly, we do not expect that any third-party payors will cover or reimburse physicians or patients for the Obalon balloon system. As a result, we expect that our success will depend on the ability and willingness of physicians that may not have historically operated a self-pay practice to adopt the policies and procedures needed to successfully operate such a practice. Our sales and marketing efforts in the United States are targeted at bariatric surgeons, gastroenterologists and plastic surgeons. Bariatric surgeons and gastroenterologists are accustomed to providing services that are reimbursed by third-party payors. As a result, these physicians may need to augment their administrative staff and billing procedures to address the logistics of a self-pay practice. If physicians are unable or unwilling to make such changes, adoption of our products may be slower than anticipated.

Our success will also depend on the ability and willingness of patients to pay out-of-pocket for treatment with our products. Adverse changes in the economy may cause consumers to reassess their spending choices and reduce the demand for elective treatments and could have an adverse effect on consumer spending. This shift could have an adverse effect on our net sales. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products. The decision by a patient to elect to undergo treatment with the Obalon balloon system may be influenced by a number of additional factors, such as:

- the success of any sales and marketing programs, including direct-to-consumer marketing efforts, that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians offer the Obalon balloon system to their patients;
- the extent to which the Obalon balloon system satisfies patient expectations;

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

Our financial performance will be materially harmed if we cannot generate significant physician or patient demand for the Obalon balloon system.

We have limited experience manufacturing our Obalon balloon system in commercial quantities and may experience production delays or issues in our manufacturing organization and be unable to meet current or future demand.

Prior to 2017, the majority of our product sales had been to a single international distributor in the Middle East. We first sold our products to physicians and institutions in the United States in 2017, and we anticipate the United States to be our primary market focus going forward. We transitioned to production of the current generation of the Obalon balloon system in November 2016. As a result, we have limited experience in manufacturing the current Obalon balloon system in commercial quantities, and we will need to increase our manufacturing capabilities in order to satisfy expected demand for our Obalon balloon system. In addition, our current generation international Obalon balloon, which we began shipping in 2017, utilizes a different catheter and dispenser configuration from our U.S. product, which we have limited experience manufacturing in commercial quantities. We have not begun commercial manufacturing for our next generation Obalon Navigation System balloon, which has not been approved by the FDA. We may find that we are unable to successfully manufacture the balloon kit in sufficient quantities or at a reasonable cost. We may need to increase our manufacturing capabilities in order to satisfy expected demand for our Obalon Navigation System balloon if FDA approved. In addition, the Obalon Navigation System balloon utilizes a different catheter and dispenser configuration from our current U.S. product, which we have limited experience manufacturing in commercial quantities. We have and may continue to 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;
- production delays or stoppages caused by receiving components or supplies which do not meet our quality specifications;
- delays that we may experience in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;
- delays that we may experience in seeking FDA review and approval of PMA supplements required for certain changes in manufacturing facilities, methods or quality control procedures;
- our limited experience in complying with the FDA's Quality System Regulation, or the QSR, which sets forth good manufacturing practice requirements for medical devices and applies to the manufacture of the components of our Obalon balloon system;
- our ability to attract, train, and retain qualified employees, who are in short supply, in order to increase our manufacturing output;
- our ability to design and validate processes to allow us to manufacture future generations of the Obalon balloon system that meets or exceeds our quality specifications in an efficient, cost-effective manner;
- our ability to produce commercial product that meets or exceeds our manufacturing specifications and release criteria;
- production delays or stoppages caused by malfunction of production equipment and/or malfunction of the electrical, plumbing, ventilation, or cooling systems supporting our manufacturing facility; and
- production stoppages and/or product scrap caused by positive tests for objectionable organisms on our products.

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

We depend on third-party suppliers, including single source suppliers, to manufacture some of our components and sub-assemblies, which could make us vulnerable to supply shortages, interruptions in production and price fluctuations that could harm our business.

We currently manufacture our Obalon balloon system and some of its components and sub-assemblies at our Carlsbad facility and we rely on third-party suppliers for other components and sub-assemblies used in production. In some cases, these suppliers are single source suppliers. For example, we rely on single suppliers for the extruded film, swallowable capsule, molded silicone valve used to manufacture our Obalon balloons and the hydrophilic coating for our catheters. We would also rely on additional single source suppliers for components of our Obalon Navigation System balloons and console. These components are critical to our current and future products and there are relatively few alternative sources of supply. We do not carry a significant inventory of these components and obtaining additional components may require significant lead-time. We have experienced and may continue to experience production challenges due to shortages of key components from suppliers. 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 our Obalon balloon system is a PMA approved product, any replacement supplier will have to be assessed by us through audits and other verification and assessment tools and found capable of producing quality components that meet our approved specifications, and we may be required to notify or obtain approval from the FDA for a change in a supplier prior to our ability to use the components it provides. If we were unable to find a replacement supplier, it could result in significant delays as we would be unable to produce additional product until such replacement supplier had been identified and qualified. If an existing or replacement supplier proposes to change any component specifications or quality requirements, the change may require FDA approval of a PMA supplement. If a supplier changes a component without notifying us, that change could result in an undetected change being incorporated into the finished product. Once detected and investigated, if the change is found to potentially affect the safety or effectiveness of the product, we would have to take corrective and preventive action, including possibly recalling the product, which could be time-consuming and expensive, and could impair our ability to meet the demand of our customers and harm our business and reputation.

In addition, our reliance on third-party suppliers for current and future products subjects us to a number of risks that could impact our ability to manufacture our products 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 produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability 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;
- delays in delivery by our suppliers due to changes in demand from us or their other customers; and
- decisions by suppliers to exit the medical device business or discontinue supplying us.

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

All of our international revenue is derived from a single distributor and sales to this distributor accounts for a significant amount of our total revenue.

Bader Sultan & Bros. Co. W.L.L., or Bader, is currently the sole distributor of our Obalon balloon system in the Middle East and our sole international customer. Sales to Bader represented 45.4% and 16.7% of our total revenue for the nine months ended September 30, 2018 and for the year ended December 31, 2017, respectively. We have limited control over Bader's sales and marketing efforts for our product. If Bader fails to effectively market and sell our products in full compliance with applicable laws, or if we are unable to maintain our existing relationship with Bader, we may not be able to find a distributor with the scale and resources of Bader, maintain existing levels of international revenue or realize expected long-term international revenue growth. In addition, since the Obalon balloon system is our sole source of revenue, a 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. The current agreement with Bader expires on December 31, 2019. Our revenues would be negatively impacted if we and Bader cannot reach a new agreement.

We do not currently intend to devote significant additional resources in the near-term to market our Obalon balloon system internationally, which will limit our potential revenue from our product.

Marketing our Obalon balloon system outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our longer term product development and regulatory strategy, we 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 generally and the market for weight loss devices specifically, are highly competitive, subject to rapid change and significantly affected by new product introductions, results of clinical research, corporate combinations, actions by regulatory bodies, changes by public and private payers and other factors. Because of the market opportunity and the high growth potential of the non-surgical device market for weight loss and obesity, competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products.

In the United States, our product competes with a variety of pharmaceuticals, surgical procedures and devices for the treatment of obese and overweight people. There are several competitors in the pharmaceutical segment including Vivus, Inc., Eisai Co., Ltd, Inc., Orexigen Therapeutics, Inc., 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. In addition, we are aware of at least two manufacturers of FDA approved balloon devices for treating overweight people, including the ReShape Duo Balloon, manufactured by ReShape LifeScience and the ORBERA Balloon, manufactured by Apollo EndoSurgery, Inc., both of which use a liquid-filled intragastric balloon. Outside of the United States, Allurion Technologies, Inc. has developed a swallowable, passable liquid-filled intragastric balloon that has been approved for sale in Europe and the Middle East and completed enrollment in a U.S. clinical trial; and Spatz Medical has also developed a liquid-filled intragastric balloon that has been approved for sale in Latin America and Europe and is currently engaged in a U.S. clinical trial. We also compete against ReShape LifeSciences' Maestro device, which is intended to create weight loss by vagal nerve stimulation and Aspire Bariatrics' ApireAssist device. Additionally, we are aware of numerous companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, any of which, if approved, could compete with us in the future.

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

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

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

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

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

We 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 and suppliers, 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, hurricane, terrorism, flooding and power outages. Any of these may render it difficult or impossible for us to manufacture products for an extended period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products, particularly as the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems would require FDA review and approval of a PMA supplement.

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

To execute our business and growth plan, we must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales and marketing personnel with experience selling and marketing directly to physicians and institutions and/or patients. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. In the first half of 2018, we accepted the resignation of our Vice President of Sales and Vice President of Marketing, though both positions have since been filled. We have also experienced turnover in our field sales force and marketing team, which could impact revenues. Replacing these individuals, and other executive officers and key employees that may depart, 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, 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 and a limited history as a commercial company selling 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 and the need to design and implement efficient, scalable processes. In addition, rapid and significant growth will place a strain on our administrative personnel, information technology systems, manufacturing operations, 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 while still producing product that meets or exceeds our quality specifications. We have, and may continue to experience difficulties with yields, excess scrap, process design and validation, quality control, component supply and shortages of qualified personnel, among others. Any failure to manage our expected growth in a cost effective manner could have an adverse effect on our ability to achieve our development and commercialization goals, which in turn could adversely impact our business and results of operations.

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

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

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

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to help facilitate the clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and to comply with applicable regulations and standards, commonly referred to as good clinical practices, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product properly and on time. While we will have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful to support product approval of a commercially viable product, or at all, and we may have to conduct additional

studies, which would significantly increase our costs, in order to obtain the regulatory clearances or approvals that we need to commercialize our products and delay commercialization.

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, design or labeling defects with the Obalon balloon system or deficiencies of other products in the intragastric balloon category. Recalls of our Obalon balloon system would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. 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 manufacturing, marketing and selling of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in our products. Claims may be made by patients, healthcare providers or others selling our products. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient.

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

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

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

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

- impairment of our brand and business reputation;
- costly litigation;
- distraction of management’s attention from our primary business;
- loss of revenue;
- the inability to commercialize our product;
- decreased demand for our product;
- product recall or withdrawal from the market;

- withdrawal of clinical trial participants; and
- substantial monetary awards to patients or other claimants.

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

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

If 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.

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

If we are unable to demonstrate that any adverse events are not related to our product, the FDA or other regulatory authorities could order us to cease further development of, require more restrictive indications for use and/or additional warnings, precautions and/or contraindications in the labeling than originally required, or delay or deny approval of any of our future products. Even if we are able to do so, such event could affect patient recruitment or the ability of enrolled patients to complete a clinical trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our products, the commercial prospects of such product may be harmed and our ability to generate product revenues from our product may be delayed or eliminated. Any of these occurrences may harm our ability to develop other products, and may harm our business, financial condition and prospects significantly.

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

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

- we could be sued and held liable for injury caused to individuals using our product; and
- our reputation may suffer.

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

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

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

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

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

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

If we experience any of these events, our business, results of operations and financial condition may be 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 September 30, 2018, we had $10.0 million in principal and interest outstanding under our loan and security agreement (the "Loan Agreement") with Pacific Western Bank (as successor-in-interest to Square 1 Bank). We also have an additional $10.0 million available to us pursuant to an amendment to the Loan Agreement, which has not been drawn down. Under the amendment, we are required to make interest-only monthly payments on the outstanding debt through July 2019, followed by 36 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. The Loan Agreement also states that our accounts maintained with the bank contain an aggregate balance in an amount equal to or greater than the total amount of outstanding debt under the Loan Agreement. These covenants may make it difficult to operate our business. We are also subject to standard event of default provisions under the Loan 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 Loan 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, quality assurance, clinical data, and customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or other catastrophic events. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks.

The failure of our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could also incur liability. Any of these events could have a material adverse effect on our reputation, business, financial condition and results of operations.

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

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

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

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

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

We are currently selling our product primarily to physicians and institutions in the United States. In connection with each sale, we typically provide credit to customers on a short term basis with payment typically due within 30 days of invoicing. In the past we have experienced and may continue to experience the need to write off accounts receivable due to the inability to collect outstanding customer balances. The inability to collect accounts receivable has and may continue to have a negative impact on our results of operations.

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

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

Clinical development of Class III medical device systems and accessories such as the Obalon balloon system is a rigorous, lengthy, expensive and uncertain process. It is also subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical data will be found reliable by the FDA, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities and support product approval. Successful results of pre-clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, the FDA or foreign regulatory authorities may disagree with our analyses and interpretation of the data from our clinical trial, or may find the clinical trial design, conduct, monitoring, or results unreliable or inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of our products. The data we collect from our clinical trials may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance or approval to market our products.

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

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

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

- enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- we may have trouble in managing multiple clinical sites or adding a sufficient number of clinical trial sites;

- we may have trouble addressing any patient safety concerns that arise during the course of a clinical trial;
- we may experience delays in agreeing on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; and
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the trial patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or suffer adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delay, or result in the failure of the clinical trial.

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

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

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

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

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

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our Obalon balloon system, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify

desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

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

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

At December 31, 2017, we had federal and state net operating loss carryforwards, or NOLs, of approximately $88.8 million and $56.8 million, respectively. Each of the federal and state NOLs will begin expiring in 2028, unless previously utilized. We also had federal and California research and development tax credit carryforwards totaling $2.1 million and $2.0 million, respectively. The federal research and development tax credit carryforward will begin to expire in 2028 unless previously utilized. The California research tax credits do not expire.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. We have not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 have occurred.

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

RISKS RELATED TO REGULATORY APPROVAL

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

The successful commercialization of the Obalon balloon system is dependent on the successful development and commercialization of future devices intended to improve the safety, efficacy, ease-of-use or cost of the Obalon balloon system.

In September 2017, we submitted a PMA supplement for the Obalon Navigation System. The Obalon Navigation System has been designed to track the balloon capsule during administration and eliminate the requirement for x-ray imaging during balloon placement. In December 2017, we received a major deficiency letter from the FDA in response to this filing. In the letter, the FDA requested additional clinical data regarding the Obalon Navigation System. We have submitted additional data, including human clinical data from a large multi-center clinical study that also supports a modification to the Obalon Navigation System to be compatible with the Touch Dispenser. As a result of this change, we filed a new PMA Supplement in the third quarter of 2018 for the FDA to evaluate the Obalon Navigation System in conjunction with the use of the Obalon Touch Inflation System. In late October 2018, we received a major deficiency letter from the FDA in response to this filing requesting additional information, analysis and clarification. There was no specific request for additional human clinical data. We expect to submit a response to the deficiency letter in a timely manner with a goal to obtain a decision from the FDA on the Obalon Navigation System in the first quarter of 2019. However, we cannot accurately predict the FDA's timing for a decision or their ultimate decision.

In November 2017, we submitted a PMA supplement for the Obalon Touch Inflation System. The Obalon Touch Inflation System is our next generation inflation system that is expected to replace the EzFill inflation system used to inflate the balloon with gas. The Obalon Touch Inflation System is a refinement of the EzPz Dispenser project based on the learning from actual usage. In January 2018, we received a major deficiency letter from the FDA in response to this filing. We supplied the requested information to the FDA, and in September 2018, we received approval of a PMA supplement from the FDA for the Obalon Touch Inflation System. At this time, we intend to commercialize the Obalon Touch Inflation System only in combination with the Obalon Navigation System, if approved.

There can be no guarantee that we will receive regulatory approval for the sale and marketing of the Obalon Navigation System in the United States or in other regulatory jurisdictions outside the United States. A number of companies in the medical device field have suffered significant setbacks during evaluation due to lack of efficacy or unacceptable safety issues, notwithstanding promising preliminary results. Because we are depending on the Obalon Navigation System, the Obalon Touch Inflation System and other new products to achieve our revenue goals in future years, failure to receive FDA approval or regulatory approval in jurisdictions outside the United States, in a timely manner or at all, will harm our financial results and ability to become profitable. If we cannot sell our Obalon Navigation System, our Obalon Touch Inflation System and other new products as planned, our financial results could be harmed. Even if we obtain regulatory approval for one or more of these new products, the terms of such regulatory approval may limit our ability to successfully market the approved product.

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

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

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

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

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an

advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;

- the applicable regulatory authority may identify deficiencies in the chemistry, manufacturing and control sections of our application, our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers;
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- the FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support a PMA application.

Further, the FDA and European regulatory authorities strictly regulate the indications for use and associated promotional safety and effectiveness claims, including comparative and superiority claims vis a vis competitors' products, that may be made about products, such as the Obalon balloon system. In particular, a medical device may not be promoted for uses or indications that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. For example, we will not be able to promote or make claims for the Obalon balloon system for the treatment of patients outside of the BMI ranges specifically approved by the FDA or other regulatory authorities. In the United States, we received FDA approval of the Obalon balloon system for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40) who have failed to lose weight through diet and exercise. The Obalon balloon system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed. Our pivotal trial inclusion and exclusion criteria included patients with a BMI of 30 to 40; thus, our approved labeling is limited to the same BMI range. We also will not be able to make comparative or superiority claims for the Obalon balloon system versus other products without scientific data supporting or establishing those claims, including possibly data from head-to-head clinical trials if appropriate. Our CE mark label includes patients with a BMI of 27 or greater.

As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at up 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 began patient enrollment in the post-approval study in the second quarter of 2018. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies, obtaining results different than our pivotal trial results or failure to comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

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

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 approval that could significantly affect its safety or effectiveness requires approval from the FDA pursuant to a PMA supplement. An applicant may make a change in a device approved through a PMA without submitting a PMA supplement if the change does not affect the safety and effectiveness of the device and the change is reported to FDA in a post-approval periodic report required as a condition of approval. We may not be able to obtain additional premarket approvals for new products or obtain approval of PMA supplements for modifications to, or additional indications for, our Obalon balloon system in a timely fashion, or at all. Delays in obtaining required future approvals would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. If we make additional modifications in the future that we believe do not or will not require additional approvals and the FDA disagrees and requires new approvals for the modifications, we may be required to recall and to stop selling or marketing our Obalon balloon system

as modified, which could harm our operating results and require us to redesign our Obalon balloon system. 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.

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

In addition, as a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at up 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 began patient enrollment in the post approval study in the second quarter of 2018. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data, when 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 publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall, which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases, or administrative or judicial enforcement actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

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

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, 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.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

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

In order to market our products in the European Union, the Middle East or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance or approval. Foreign regulatory approval processes include many of the risks associated with obtaining FDA clearance or approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance or approval does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration.

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

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, inspection, complaint handling, record keeping, management review, labeling, packaging, sterilization, storage and shipping of our Obalon balloon system. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive record keeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by

governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we are found to not be in compliance at the conclusion of an FDA QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, issuance of a Warning Letter, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenues to decline.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA numerous times, the most recent of which occurred in 2017, with zero inspectional observations noted. 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 U.S. federal healthcare programs (such as Medicare or Medicaid) or other third-party payors, any future reimbursement by third-party payors could expose our business to broadly applicable fraud and abuse and other healthcare laws and regulations that would regulate the business, including laws that would regulate financial arrangements and relationships through which we market, sell and distribute the Obalon balloon system. Additionally, as a device manufacturer,

we are still subject to certain healthcare fraud and abuse regulation, including those laws that apply to self-pay products, and enforcement by the federal government and the states in which we conduct our business.

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

- ***Anti-Kickback Laws.*** The federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare and Medicaid, unless the arrangement fits within one of several statutory exceptions or regulatory "safe harbors." Courts have interpreted the term "remuneration" broadly under the Anti-Kickback Statute to include anything of value, such as, for example, gifts, discounts, payments of cash and waivers of payments. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare programs. Exclusion of a manufacturer would preclude any federal healthcare program from paying for the manufacturer's products. A person does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, kickback arrangements can provide the basis for an action under the False Claims Act, which is discussed in more detail below.

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

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

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

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

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

- ***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. 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, 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 September 30, 2018, we held 18 issued U.S. patents and had 31 pending U.S. patent applications, as well as 28 international patents issued in regions including Europe, Mexico, Australia, Canada, Asia, China and Israel and 47 pending international patent applications regions including in Australia, Canada, Europe, Asia, the Middle East and South America. Our issued patents expire between the years 2023 and 2033, and are directed to various features and combinations of features of the Obalon balloon system technology, including the apparatus for connecting the balloon to an inflation catheter, the structure and composition of the balloon wall, and the composition of the initial fill gas.

As of September 30, 2018, we held two registered U.S. trademarks and 26 registered marks in Europe, the Middle East, Asia and Mexico. We have five pending U.S. trademark applications and 15 pending marks outside the United States, including in Europe, the Middle East, Asia and Mexico.

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

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

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect the Obalon balloon system or any other products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our Obalon balloon system before our relevant patents expire;
- we were the first to make the inventions 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, during 2017, we settled intellectual property infringement claims made by two separate third parties. We believed the claims in both instances were meritless but settled the matters for a nominal cash payment and aggregate stock issuances of 175,000 shares, in exchange for which we received a general release of all claims. Additionally, we have received and may from time to time in the ordinary course of business continue to receive, letters from third parties advising us of third-party patents that may relate to our business. The letters do not explicitly seek any particular action or relief from us. Although these letters do not threaten legal action, these letters may be deemed to put us on notice that continued operation of our business might infringe the patent rights of such third parties. If we decide not to seek a license or do not otherwise obtain a license to such third-party patents, there can be no assurance that we will not become subject to infringement claims or will not be forced to initiate legal proceedings in order to dispose of such actual or potential infringement claims or to seek to invalidate the claims of such third-party patents.

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

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

- be subject to a protected period of uncertainty while the claims or litigation remain unresolved, which could adversely affect our ability to raise additional capital and otherwise adversely affect our business;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; and
- be required to redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible.

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

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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

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

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

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

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

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

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

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

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

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

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

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

The United States has recently enacted and is currently implementing the America Invents Act of 2011, a wide-ranging patent reform legislation. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition

to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

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

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

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

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

- developments, announcements or disputes related to patents or other proprietary rights issued to us or our competitors and to litigation;
- ability to meet NASDAQ minimum listing requirements; and
- developments in our industry.

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

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors, and their projections of our financial results. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares, change their opinion of our shares, change their financial projections, publish negative information about us or if we are unable to achieve their financial projections for us, our share price would likely decline. 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. In addition, analysts may publish negative opinions concerning our company, business strategy or accounting policies, which could negatively impact our share price.

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

We will need additional capital in the future to continue our planned operations in addition to the proceeds we received from our initial public offering in October 2016 and a private placement in August 2018. 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. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

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

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

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value

of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

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

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

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

to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

As of September 30, 2018, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a majority of our outstanding capital stock. As a result, this group of stockholders will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are subject to securities class action litigation.

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

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

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

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

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan, also known as a "poison pill";

- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

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

Any of these provisions of our charter documents or Delaware law could, under certain circumstances, depress the market price of our common stock.

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

Our restated certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, any action asserting a claim arising pursuant to any provision of the DGCL, our restated certificate of incorporation or our restated bylaws or any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or for which the Court of Chancery does not have subject matter jurisdiction. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our restated certificate of incorporation. This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

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

We have never declared or paid any cash dividends on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. In addition, our loan and security agreement with Pacific Western Bank prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. Any return to stockholders will be limited to the appreciation of stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in the value of the stock. We cannot guarantee you that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities
None

Use of Proceeds

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

There has been no material change in the expected use of the net proceeds from our Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 5, 2018. Through September 30, 2018, approximately $51.7 million of the net proceeds have been used primarily for the commercialization of our Obalon balloon system and continued research and development efforts.

ITEM 3. Defaults Upon Senior Securities

Not applicable.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

Exhibit Number	Description of Document	Form	File No.	Exhibit Filing Date	Filed/Furnished Herewith
3.2	Restated Certificate of Incorporation	S-1	333-213551	9/26/2016	
3.4	Restated Bylaws	S-1	333-213551	9/26/2016	
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1†	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OBALON THERAPEUTICS, INC.

Date: November 2, 2018 by: /s/ Andrew Rasdal
Andrew Rasdal
Chief Executive Officer

Date: November 2, 2018 by: /s/ William Plovanic
William Plovanic
Chief Financial Officer

Exhibit 31.1

OBALON THERAPEUTICS, INC.
CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Rasdal, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2018

/s/ Andrew Rasdal

Andrew Rasdal

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

OBALON THERAPEUTICS, INC.
CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William Plovanic, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2018

/s/ William Plovanic

William Plovanic

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO SECTION 906

OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Obalon Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Andrew Rasdal, the President and Chief Executive Officer, and William Plovanic, the Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Dated: November 2, 2018

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

A signed original of this written statement required by Section 906 has been provided to Obalon Therapeutics, Inc. and will be retained by Obalon Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. These certifications will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor will these certifications be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates them by reference.