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, 2019

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)**

(844) 362-2566
(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 ☒ 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 ☒ 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	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	OBLN	The NASDAQ Stock Market LLC (NASDAQ Global Market)

Total shares of common stock outstanding as of the close of business on November 6, 2019 was 7,694,576.

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PART I. FINANCIAL INFORMATION
ITEM 1. Condensed Consolidated Financial Statements

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

	September 30, 2019	December 31, 2018
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 19,380	$ 21,187
Short-term investments	—	2,548
Accounts receivable, net of allowance of $508 and $665, respectively	238	870
Inventory	2,048	1,580
Other current assets	683	2,462
Total current assets	22,349	28,647
Property and equipment, net	1,117	1,739
Lease right-of-use assets	1,191	—
Total assets	$ 24,657	$ 30,386
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 732	$ 1,159
Accrued compensation	724	3,805
Deferred revenue	283	352
Other current liabilities	1,609	1,985
Current portion of lease liabilities	557	—
Current portion of long-term loan	—	9,930
Total current liabilities	3,905	17,231
Lease liabilities long-term	687	—
Other long-term liabilities	—	48
Total long-term liabilities	687	48
Total liabilities	4,592	17,279
Commitments and contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 7,724,100 and 2,351,333 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	8	2
Additional paid-in capital	187,574	161,859
Accumulated deficit	(167,517)	(148,754)
Total stockholders' equity	20,065	13,107
Total liabilities and stockholders' equity	$ 24,657	$ 30,386

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,	
	2019	2018	2019	2018
	(Unaudited)			
Revenue	$ 333	$ 2,987	$ 2,494	$ 7,065
Cost of revenue	412	1,418	2,323	3,919
Gross (deficit) profit	(79)	1,569	171	3,146
Operating expenses:				
Research and development	1,174	2,368	5,401	8,359
Selling, general and administrative	2,489	5,836	13,025	23,092
Total operating expenses	3,663	8,204	18,426	31,451
Loss from operations	(3,742)	(6,635)	(18,255)	(28,305)
Interest income (expense), net	37	(70)	(448)	(164)
Other expense, net	(1)	(40)	(60)	(155)
Net loss	(3,706)	(6,745)	(18,763)	(28,624)
Other comprehensive income (loss)	—	(3)	—	3
Net loss and comprehensive loss	$ (3,706)	$ (6,748)	$ (18,763)	$ (28,621)
Net loss per share, basic and diluted	$ (0.61)	$ (3.47)	$ (5.07)	$ (16.05)
Weighted-average common shares outstanding, basic and diluted	6,061,248	1,945,864	3,700,538	1,783,793

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
			(Unaudited)		
Balance at December 31, 2018	2,351,333	$ 2	$ 161,859	$ (148,754)	$ 13,107
Stock-based compensation	—	—	1,105	—	1,105
Issuance of common stock for cash upon exercise of stock options	119	—	1	—	1
Vesting of early exercised stock options	—	—	14	—	14
Issuance of common stock, net of issuance costs	75,551	1	580	—	581
Cancellation of restricted stock awards	(2,051)	—	—	—	—
Net loss	—	—	—	(8,290)	(8,290)
Balance at March 31, 2019	2,424,952	3	163,559	(157,044)	6,518
Stock-based compensation	—	—	536	—	536
Issuance of common stock for cash upon exercise of stock options	—	—	—	—	—
Vesting of early exercised stock options	—	—	15	—	15
Issuance of common stock, net of issuance costs	1,158,187	1	8,073	—	8,074
Cancellation of restricted stock awards	(24,859)	—	—	—	—
Net loss	—	—	—	(6,767)	(6,767)
Balance at June 30, 2019	3,558,280	$ 4	$ 172,183	$ (163,811)	$ 8,376
Stock-based compensation	—	—	659		659
Costs associated with issuance of common stock	—	—	(7)	—	(7)
Vesting of early exercised stock options	—	—	14	—	14
Issuance of common stock and warrants, net of issuance costs	2,427,500	2	14,716		14,718
Exercise of warrants for the purchase of common stock	1,735,000	2			2
Issuance of round up common stock for reverse stock split	3,320	—	9		9
Net loss	—	—	—	(3,706)	(3,706)
Balance at September 30, 2019	7,724,100	$ 8	$ 187,574	$ (167,517)	$ 20,065

See accompanying notes to consolidated financial statements.

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

	Common stock		Additional paid-in capital	Accumulated other comprehensive (loss) income	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
	(unaudited)					
Balance at December 31, 2017	1,750,061	$ 2	$ 146,490	$ (5)	$ (111,374)	$ 35,113
Stock-based compensation	—	—	1,389	—	—	1,389
Issuance of common stock for cash upon exercise of stock options	2,068	—	28	—	—	28
Vesting of early exercised stock options	—	—	14	—	—	14
Issuance of restricted stock awards, net of cancellations	7,500	—	—	—	—	—
Unrealized gain on short-term investments	—	—	—	6	—	6
Net loss	—	—	—	—	(12,126)	(12,126)
Balance at March 31, 2018	1,759,629	2	147,921	1	(123,500)	24,424
Stock-based compensation	—	—	1,214	—	—	1,214
Issuance of common stock for cash upon exercise of stock options	223	—	3	—	—	3
Vesting of early exercised stock options	—	—	15	—	—	15
Issuance of common stock under ESPP	4,526	—	148	—	—	148
Issuance of restricted stock awards, net of cancellations	21,495	—	—	—	—	—
Net loss	—	—	—	—	(9,753)	(9,753)
Balance at June 30, 2018	1,785,873	$ 2	$ 149,301	$ 1	$ (133,253)	$ 16,051
Stock-based compensation		—	1,007	—	—	1,007
Issuance of common stock for cash upon exercise of stock options	310	—	7	—	—	7
Vesting of early exercised stock options	—	—	14	—	—	14
Issuance of common stock, net of issuance costs	549,451	5	9,817	—	—	9,822
Cancellation of restricted stock awards	(7,600)	—	—	—	—	0
Unrealized gain on short-term investments	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(6,745)	(6,745)
Balance at September 30, 2018	2,328,034	$ 7	$ 160,146	$ (2)	$ (139,998)	$ 20,153

See accompanying notes to consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
	(Unaudited)	
Operating activities:		
Net loss	$ (18,763)	$ (28,624)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	361	428
Stock-based compensation	2,300	3,610
Loss on disposal of fixed assets	128	107
Amortization of right-of-use asset	301	—
Accretion of investment discount, net	(2)	(20)
Amortization of debt discount	70	29
Change in operating assets and liabilities:		
Accounts receivable, net	632	1,448
Inventory	(117)	(537)
Other current assets	1,604	805
Accounts payable	(724)	135
Accrued compensation	(3,097)	(1,823)
Deferred revenue	(69)	(209)
Lease liabilities, net	(248)	—
Other current and long-term liabilities	(363)	634
Net cash used in operating activities	(17,987)	(24,017)
Investing activities:		
Purchases of short-term investments	—	(9,103)
Maturities of short-term investments	2,550	24,302
Purchases of property and equipment	(44)	(867)
Net cash provided by investing activities	2,506	14,332
Financing activities:		
Proceeds from long-term loan	10,000	—
Payment on long-term loan	(20,000)	—
Proceeds from issuance of common stock and warrants, net of paid issuance costs	15,014	—
Proceeds from issuance of common stock, net of issuance costs	8,659	9,973
Proceeds from stock issued under employee stock purchase plan	—	148
Proceeds from sale of common stock upon exercise of stock options	1	38
Fees paid in connection with loan amendment	—	(30)
Net cash provided by financing activities	13,674	10,129
Net (decrease) increase in cash and cash equivalents	(1,807)	444
Cash and cash equivalents at beginning of period	21,187	21,108
Cash and cash equivalents at end of period	$ 19,380	$ 21,552
Supplemental cash flow information:		
Interest paid	$ 700	$ 473
Unpaid issuance costs	$ 295	$ 160
Property and equipment in accounts payable	$ —	$ 106

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

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

Reverse Stock Split

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

Liquidity

As of September 30, 2019, the Company has devoted a substantial portion of its efforts to product development, raising capital, and building infrastructure, and, since January 2017, U.S. commercialization. The Company has incurred operating losses and has experienced negative cash flows from operations since its inception. In July 2012, the Company realized initial revenue from its planned principal operations. The Company recognized total revenue of $0.3 million and $3.0 million for the three months ended September 30, 2019 and 2018, respectively, and $2.5 million and $7.1 million for the nine months ended September 30, 2019 and 2018, respectively. However, the Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and has funded its activities to date almost exclusively from debt and equity financings.

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, 2019, its accumulated deficit was $167.5 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 public and private placements, and, to a lesser extent, debt financing arrangements.

In August 2019, the Company issued and sold an aggregate of (i) 2,427,500 shares of its common stock (including412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of common stock, (iii) accompanying warrants to purchase up to 3,234,375 shares of common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) and (iv) an additional warrant to the underwriters for the purchase37,500 shares of common stock, for net proceeds from the offering of approximately $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. As of September 30, 2019, the Company had cash and cash equivalents of $19.4 million. Additionally, during the second quarter of 2019, the Company paid down $15.0 million of the principal balance due under the loan and security agreement with Pacific Western Bank (as successor-in-interest to Square 1 Bank) and during the third quarter of 2019, the Company paid down the remaining $5.0 million of principal balance due under the loan and security agreement with Pacific Western Bank, thereby removing the risks and restrictions of carrying long-term debt. See Note 8 for further detail regarding the equity financing transactions.

In an effort to address the Company's liquidity concerns, and pay expenses relating to its operating activities, including selling, general and administrative expenses and research and development expenses, on April 2, 2019, the Company commenced an

internal restructuring and notified approximately 49 employees, or approximately 50% of the Company's workforce, that their employment would be terminated. This restructuring included the elimination of the Company's field sales force and a transition to more centralized customer support and marketing program strategy. Going forward, rather than focusing on selling to physicians, the Company intends to focus its commercialization efforts on the establishment and operation of company-owned or managed Obalon-branded retail treatment centers.

The consolidated financial statements as of and for the nine months ended September 30, 2019 have been prepared on the basis that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Based on the Company's cash balances and recurring losses since inception, there is substantial doubt about its ability to continue as a going concern and if the Company is not able to continue to raise sufficient capital, it will not be able to support ongoing operations.

2. Summary of Significant Accounting Policies

Except for the operating lease policy described below, there were no significant changes to the accounting policies during the nine months ended September 30, 2019, 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, 2018, filed on February 22, 2019.

Leases

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

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

Variable Interest Entities

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

Revenue Recognition

The Company recognizes revenue, in accordance with ASC 606, when control of its products is transferred to its customers in an amount that reflects the consideration it expects to receive in exchange for those products. The Company's revenue recognition process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the transaction price, allocating the transaction price to the distinct performance obligations in the contract, and recognizing revenue as performance obligations are satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation

satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Revenue is 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 contract. 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 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, 2019 and for the three and nine months ended September 30, 2019 and 2018 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, 2019 and its condensed consolidated results of operations for the three and nine months ended

September 30, 2019 and 2018, statements of stockholders' equity for the three and nine months ended September 30, 2019 and 2018, and cash flows for the nine months ended September 30, 2019 and 2018. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The balance sheet as of December 31, 2018 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, 2018, filed on February 22, 2019.

Fair Value Measurements

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

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

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

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 revenue and accounts receivable.

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenue	2019	2018	2019	2018
Customer A	— %	39.4 %	23.6 %	45.4 %
Customer B	25.1 %	0.5 %	4.3 %	0.8 %
Customer C	22.4 %	4.7 %	21.4 %	3.9 %
Customer D	11.4 %	— %	2.0 %	0.2 %

Accounts Receivable	September 30, 2019	December 31, 2018
Customer B	21.2 %	0.9 %
Customer D	10.8 %	1.5 %

The Company's largest customer for the nine months ended September 30, 2019 and the largest customer for the three and nine months ended September 30, 2018 was its Middle East distributor. There were no other international sales aside for the nine months ended September 30, 2019, aside from sales to this distributor during the three months ended March 31, 2019.

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

Recently Issued Accounting Pronouncements not yet adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13,*Financial Instruments - Credit Losses*, which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company believes the adoption will modify the way the Company analyzes financial instruments, but it does not anticipate a material impact on results of operations. The Company is in the process of determining the effects the adoption will have on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13,*Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted-average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. The Company is currently evaluating this guidance to determine the impact, if any, it may have on its condensed consolidated financial statements.

3. Fair Value Measurements

Instruments Recorded at Fair Value on a Recurring Basis

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

Assets and liabilities measured at fair value on a recurring basis as ofSeptember 30, 2019 and December 31, 2018 are as follows (in thousands):

		Fair value measurements at reporting date using		
	Balance as of September 30, 2019	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	$ 19,380	$ 19,380	$ —	$ —
Total assets	$ 19,380	$ 19,380	$ —	$ —

		Fair value measurements at reporting date using		
	Balance as of December 31, 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	$ 21,187	$ 21,187		
Short-term investments:				
U.S. Treasury bonds	2,548	2,548	$ —	$ —
Total assets	$ 23,735	$ 23,735	$ —	$ —

The Company’s investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as ofSeptember 30, 2019 and December 31, 2018.

Instruments Not Recorded at Fair Value on a Recurring Basis

The estimated fair value of the Company's short-term loan as of December 31, 2018 is determined by Level 2 inputs and is based primarily on quoted market prices for the same or similar issues. The recorded value of the Company's short-term loan approximates the current fair value as the interest rate and other terms are that which are currently available to the Company.

4. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (3,706)	$ (6,745)	$ (18,763)	$ (28,624)
Weighted-average common shares outstanding, basic and diluted	6,061,248	1,945,864	3,700,538	1,783,793
Net loss per share, basic and diluted	$ (0.61)	$ (3.47)	$ (5.07)	$ (16.05)

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,	
	2019	2018	2019	2018
Stock options to purchase common stock	8	25,968	5,328	42,473
Total	8	25,968	5,328	42,473

5. Balance Sheet Details

Inventory consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	$ 1,885	$ 1,090
Work in process	78	288
Finished goods	85	202
Total	$ 2,048	$ 1,580

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

	September 30, 2019	December 31, 2018
Prepaid expenses	$ 656	$ 2,329
Interest receivable	—	12
Other assets	27	121
Total	683	$ 2,462

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

	September 30, 2019	December 31, 2018
Computer hardware	$ 259	$ 410
Computer software	291	274
Leasehold improvements	422	405
Furniture and fixtures	179	178
Scientific equipment	1,993	1,921
Construction in progress, or CIP	180	530
	3,324	3,718
Less: accumulated depreciation	(2,207)	(1,979)
Total	$ 1,117	$ 1,739

Depreciation expense was $0.1 million for each of the three months ended September 30, 2019 and 2018, respectively, and $0.4 million for both the nine months ended September 30, 2019 and 2018.

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

	September 30, 2019	December 31, 2018
Accrued legal and professional fees	$ 637	$ 624
Accrued customer incentives	178	467
Accrued sales and other taxes	118	132
Other accrued expenses	676	762
Total	$ 1,609	$ 1,985

6. Term Loan

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

In July 2018, the Company executed the Fifth Amendment to the Loan and Security Agreement (the "Loan Amendment") with Pacific Western Bank, which increased the loan capacity to $20 million from $10 million. The loan capacity of $20 million consists of two tranches as follows: a first tranche consisting of $10.0 million funded on July 10, 2018, of which the full $10.0 million was required to settle the existing debt with Pacific Western Bank on a net settlement basis (pursuant to its original terms); and a second tranche consisting of an additional $10.0 million which may be drawn at any time prior to July 9, 2019. During the first quarter of 2019, the Company drew down on the remaining $10.0 million tranche. During the second quarter of 2019, the Company paid down $15.0 million of the principal balance due under the Loan Agreement. During the third quarter of 2019, the Company paid down the remaining $5.0 million of principal balance due under the term loan, thereby removing the risks and restrictions of carrying long-term debt. As of September 30, 2019, the Company had no outstanding borrowings under the Loan Agreement.

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

Upon repayment of the outstanding debt in full, the Loan Agreement was terminated and the Company is no longer subject to the covenants and restrictions set forth in the Loan Agreement.

The loan fee paid and the remaining balance of debt issuance costs and debt discount on the previous loan agreement held with Pacific Western Bank were amortized to interest expense during the third quarter of 2019. As of September 30, 2019, there were no unamortized debt issuance costs due to the $15.0 million and $5.0 million payments on the Company's term loan in the second and third quarters of 2019, respectively.

7. Stock-Based Compensation

Equity Incentive Plan

As of September 30, 2019, 78,771 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 total non-cash compensation, including non-cash compensation to employees and nonemployees in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of revenue	$ 5	$ 28	$ (21)	$ 68
Research and development	158	307	568	859
Selling, general and administrative	496	672	1,753	2,683
Total	$ 659	$ 1,007	$ 2,300	$ 3,610

Unrecognized stock-based compensation expense at September 30, 2019 was approximately $2.2 million, which is expected to be recognized over a weighted-average term of 2.25 years.

Incentive Stock Options

The following table summarizes stock option transactions for the 2016 Equity Incentive Plan for the nine months ended September 30, 2019 (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, 2018	336,008	$ 58.29		
Options granted	159,765	17.16		
Options exercised	(118)	8.72		
Options canceled	(50,621)	45.45		
Outstanding at September 30, 2019	445,034	$ 45.00	6.55	$ —
Vested and expected to vest at September 30, 2019	409,978	$ 46.33	6.52	$ —
Vested and exercisable at September 30, 2019	254,911	$ 52.52	6.29	$ —

Restricted Stock Awards

The following table summarizes restricted stock award transactions for the 2016 Equity Incentive Plan for the nine months ended September 30, 2019:

	Number of awards	Weighted-average grant date fair value
Outstanding at December 31, 2018	61,198	$ 58.85
Awards granted	—	—
Awards released	(4,750)	71.50
Awards canceled	(26,924)	77.70
Outstanding at September 30, 2019	29,524	$ 39.64

Restricted Stock Units

The following table summarizes restricted stock unit transactions for the 2016 Equity Incentive Plan for the nine months ended September 30, 2019:

	Number of shares	Weighted-average grant date fair value	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2018	—	$ —	
Awards granted	55,574	11.70	
Awards released	—	—	
Awards canceled	—	—	
Outstanding at September 30, 2019	55,574	$ 11.70	$ 108
Vested and expected to vest at September 30, 2019	49,114	$ 11.87	$ 95

8. Stockholder's Equity

Public Offering and related warrants

On August 1, 2019, the Company entered into an underwriting agreement with A/G.P./Alliance Global Partners, as underwriter, in connection with a public offering of the Company's securities, pursuant to which the Company issued and sold (i) 2,427,500 shares of common stock (including412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of common stock ("Pre-funded Warrants"), (iii) accompanying warrants to purchase up to3,234,375 shares of common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) ("Purchase Warrants") and (iv) an additional warrant to the underwriters for the purchase 37,500 shares of common stock ("Representative Warrant"). The offering was made pursuant to a registration statement on Form S-1. The offering closed on August 6, 2019 resulting in net proceeds of approximately $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The shares of common stock and accompanying Purchase Warrants were sold at a public offering price of $4.00 per share, the Pre-funded Warrants and accompanying Purchase Warrants were sold at a public offering of$3.999. The Purchase Warrants were immediately exercisable upon issuance, will expire on August 6, 2024 and have an exercise price of $4.40 and the Representative Warrant has an exercise price of $5.00, in each case subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events. The Representative Warrant is exercisable in February 2020 and expires on August 6, 2024. All of the Pre-funded warrants were exercised during the third quarter of 2019. None of the Purchase or Representative Warrants have been exercised as of September 30, 2019. All of the warrants are recorded within equity in accordance with authoritative accounting guidance.

Securities Purchase Agreement

On May 23, 2019, the Company entered into a Securities Purchase Agreement with certain investors for the sale by the Company of500,000 shares of the Company's common stock, par value $0.001 per share, at a purchase price of $6.00 per share. The closing of the sale of the shares under the Securities Purchase Agreement occurred on May 28, 2019. The Company incurred $0.4 million of legal, accounting and other professional fees related to the Securities Purchase Agreement. The aggregate gross proceeds for the sale of the shares was $3.0 million.

Equity Distribution Agreement

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

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

The Company incurred $0.2 million of legal, accounting and other professional fees related to the Equity Distribution Agreement. These amounts are included as deferred charges within other current assets on the Company's condensed consolidated balance sheet as of September 30, 2019 and all were charged against paid-in capital upon receipt of proceeds from the sale of common stock under the Equity Distribution Agreement. As of September 30, 2019, the Company has sold 377,615 shares under the Equity Distribution Agreement for aggregate gross proceeds of $2.8 million.

Lincoln Park Purchase Agreement

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

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

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

The Company incurred $0.8 million of commitment shares issued, legal, accounting, registration and other professional fees related to the Lincoln Park Purchase Agreement. These amounts are included as deferred charges within other current assets on the Company's balance sheet as of September 30, 2019 and all were charged against paid-in capital upon receipt of proceeds from the sale of common stock under the Lincoln Park Purchase Agreement. As of September 30, 2019, the Company has sold

356,122 shares under the Lincoln Park Purchase Agreement for aggregate gross proceeds of$4.2 million. No future issuances are anticipated under this agreement.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following as ofSeptember 30, 2019:

Stock options issued and outstanding	445,034
Restricted stock units issued and outstanding	55,574
Warrants for the purchase of common stock	3,271,875
Authorized for future option and ongoing vesting of award grants	78,771
Authorized for future issuance under ESPP	74,520
Total	3,925,774

9. Income Taxes

For the three and nine months September 30, 2019 and 2018, 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

Operating Leases

The Company leases its facilities and retail treatment center under noncancelable operating leases which expire on various dates between 2021 and 2022. In July 2019, the Company entered into an office lease agreement to launch an Obalon-branded retail treatment center in San Diego, California, which expires on August 5, 2021. Under the terms of the facilities and retail center leases, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs. Upon the Company's adoption of ASC 842 as of January 1, 2019, the Company recognized a ROU asset and lease liability for its building lease, assuming a 7.0% discount rate. Any short-term leases defined as 12 months or less or month-to-month leases were excluded and continue to be expensed each month. Total costs associated with short-term leases for the three and nine months ended September 30, 2019 were immaterial.

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

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

Future minimum annual lease payments under such leases are as follows as of September 30, 2019 (in thousands):

Undiscounted lease payments:		
Remainder of 2019	$	137
2020		569
2021		533
2022		117
Total undiscounted lease payments		1,356
Less: imputed interest		(112)
Lease liability		1,244
Less: current portion of lease liability		(557)
Lease liability, less current portion	$	687

As of September 30, 2019, the Company's remaining lease terms range from 1.9 to 2.5 years. Rent expense totaled $0.2 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $0.4 million and $0.2 million for the nine months ended September 30, 2019 and 2018, respectively. The Company paid $0.1 million and $0.2 million of cash payments related to its operating lease agreement for the three and nine months ended September 30, 2019, respectively.

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

Pursuant to the Company's supplier agreement entered into in December 2018, the Company is obligated to purchase certain minimum quantities. These costs scale up as the Company's projected manufacturing volume increases. Under the terms of the agreement, the Company can reduce the forecasted minimum quantities and is required to incur a holding fee for items manufactured by the supplier. This represents the one year minimum commitment of approximately $1.5 million as of September 30, 2019.

Termination of Stock Offering

On January 23, 2018, the Company issued a press release announcing the termination of its previously announced offering of common stock due to a purported whistleblower compliant, which was later found to be without merit. As of September 30, 2019, the Company did not record any liability associated with termination of the offering, and management believed that the likelihood is remote that the Company will incur material fees in the future.

Shareholder Lawsuit

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against 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 underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation.

On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims. The Company believes the remaining claims in the complaint are without merit and intends to defend vigorously against them.

11. Variable Interest Entity

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

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

For the three months ended September 30, 2019, the PC recognized an immaterial amount of deferred revenue associated with prepaid services at the treatment center, which is fully presented in the condensed consolidated balance sheet of the Company at September 30, 2019.

12. Restructuring Charges

2019 Restructuring Activities

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

	Nine Months Ended September 30, 2019
Employee separation costs	$ 1,008
Asset disposals	91
Total	$ 1,099

In April 2019, the Company notified approximately 49 employees whose employment will be terminated, or approximately 50% of its workforce, with the intent to refocus activities, streamline operations and make more efficient use of cash. As a result of the workforce reduction, the Company recorded a restructuring charge in April 2019 for termination benefits of $0.5 million which has been paid as of September 30, 2019. Additionally, as a result of the workforce reduction, the Company recognized a reversal of stock-based compensation expense of $0.8 million in April of 2019 and a $0.1 million restructuring charge in connection with the disposal of assets related to the terminated employees.

In May and June 2019, the Company accepted the voluntary resignations of its President and Chief Executive Officer and its Vice President of Research and Development. As part of the resignations, each former officer entered into a consulting agreement for a term of 12 months, which allows for the continuous vesting of stock awards held over the consulting term and a monthly, fixed consulting fee. No severance amounts were granted. The Company recorded a restructuring charge in June 2019 for the full consulting benefits of $0.6 million and an immaterial amount of this charge has been paid as of September 30, 2019. Additionally, the Company recognized the full stock-based compensation expense of $0.7 million.

No further restructuring charges were recorded in the third quarter of 2019. For the nine months ended September 30, 2019, the following restructuring charges were included in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Nine Months Ended September 30,
	2019
Cost of revenue	$ 53
Research and development	370
Selling, general and administrative	676
Total	$ 1,099

Activity and restructuring charge reserve balance as of September 30, 2019 were as follows:

	Employee separation costs
Reserve balance at December 31, 2018	$ —
2019:	
Restructuring charges	1,105
Cash payments	(537)
Reserve balance at June 30, 2019	$ 568
Cash payments	(144)
Reserve balance at September 30, 2019	$ 424

13. Subsequent Event

On October 19, 2019, the Company’s Board of Directors approved the promotion of William Plovanic to Chief Executive Officer from his prior role of Chief Financial Officer. Mr. Plovanic will retain the title of President and continue to serve as a Class II director on the Board. In addition, the Company promoted Nooshin Hussainy to Chief Financial Officer from her prior role of Vice President Finance and Controller. Concurrent with these promotions, the Company's Board of Directors approved stock option awards covering 74,682 shares of common stock to certain of the Company's executive officers and employees.

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, selection of specific financial and strategic alternatives, 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, 2018, included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed on February 22, 2019.

OVERVIEW

We are a vertically integrated medical device company focused on developing and commercializing innovative medical devices to treat people with obesity. 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 patients with obesity. We believe the Obalon Balloon System offers patients and physicians benefits over prior weight loss devices including, but not limited to: a favorable safety profile, improved patient tolerability and comfort, progressive weight loss with durable results, simple and convenient placement, and potentially attractive economics for patients and physicians.

The Obalon Balloon System is FDA approved for temporary use to facilitate weight loss in adults with obesity having a body mass index, or BMI, of 30 to 40, or approximately 30 to 100 pounds overweight, who have failed to lose weight through diet and exercise alone. The system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed in six months after the first balloon is placed. We believe the Obalon Balloon System may provide patients and physicians with a cost-effective, reversible and repeatable weight loss solution that can be delivered in an outpatient setting, without altering patient anatomy or requiring surgery.

The current generation of our Obalon Balloon System consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Navigation System console, which is a combination of hardware and software used to track and display the location of the balloon during placement; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas. Placement of a balloon typically occurs in less than 10 minutes and can be accomplished in an outpatient setting. Patients

receive a total of three balloons over the course of eight to 12 weeks and all balloons are removed six months after the first balloon is placed.

The Obalon Balloon System has demonstrated progressive weight loss with durable results. In our SMART trial, patients in the Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham-control group. In addition, patients in the Obalon treatment group showed, on average, progressive weight loss over the entire six-month balloon treatment period, and maintained, on average, 89.5% of the weight loss six months after balloon removal. In December 2018, we analyzed data from our commercial registry on more than 1,300 patients at 108 treatment sites. For those patients who received three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in 9.9% reduction in total body weight and a 3.5 point decrease in BMI compared to baseline values. Of note, the top quartile of those patients lost an average of 39 pounds, resulting in a 16.8% reduction in total body weight and a 6.2 point decrease in BMI compared to baseline values. Furthermore, in May 2019, additional data was presented, which included additional data analysis from our commercial registry of 1,411 total patients from 143 treatment sites in the United States. In this larger data set, for those patients receiving three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in a 10.2% reduction in total body weight. Of note, 50.7% of patients lost 10% or more total body weight and 77.9% lost 5% or more total body weight. Weight loss in the first months of therapy was the largest predictor of success.

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

Historically we have sold our products directly to physicians, who would then sell weight loss treatment packages to their patients that included our balloon therapy, dietary counseling and balloon removal on a non-reimbursed, self-pay basis. Beginning in April 2019, we began to fundamentally change our commercialization efforts, and eliminated our direct sales force in connection with an overall workforce reduction in April 2019. Concurrent with our workforce reduction, we transitioned to a centralized customer support model through which we sell to existing physicians that are using our balloons or new physicians that contact us directly to acquire our system and balloons, and provide marketing and clinical support to those physicians. Marketing support may include media assets and media purchasing support and leads generated from our Find-A-Doc locator. In addition, rather than focusing on selling directly to physicians, we intend to establish company-owned or managed Obalon-branded retail treatment centers, the first of which began operations in late September 2019. Under this new model, we plan to either directly employ physicians or manage the practices where the treatments are prescribed by physicians, and we will be directly responsible for practice marketing and promotion efforts. We expect to provide the physician office support staff, equipment and services necessary for patients to receive the Obalon balloon therapy from licensed physicians. We began operating of our first Obalon-branded retail treatment center in September 2019. We are in the early stages of this transition and cannot predict whether it will be an effective means of selling the Obalon Balloon System. We believe this model will contribute to standardization of both quality of care and patient pricing and provide us greater operational and financial control of our business.

We intend to continue to drive patient awareness and interest in part through multiple efforts that may vary over time and may include digital, offline and social marketing. We estimate that there were more than 49 million views of our digital advertisements and more than 6 million views of our digital videos in 2018. We also estimate that visits to our website were 1.7 million in 2018 and searches of our website for physicians capable of placing our Obalon Balloon System were over 580,000 in 2018. We also generated over 71,000 patient leads to our physician partners in the United States during 2018. During the nine months ended September 30, 2019, we estimate there were approximately 9.3 million views of our digital advertisements, more than 3.3 million views of our digital videos, over 285,000 visits to our website, over 38,000 searches of our website for physicians capable of placing our Obalon Balloon System and generated approximately 21,000 patient leads to our physician partners in the United States. There was a significant reduction in spending for digital, offline and social marketing in the second quarter of 2019 due to the change in commercialization efforts. In the third quarter of 2019 we initiated digital marketing programs in support of the Obalon-branded retail treatment center, whixh we refer to as the Obalon Center for Weight Loss.

We generated total revenue of $0.3 million and $3.0 million for the three months ended September 30, 2019 and 2018, respectively, and $2.5 million and $7.1 million for the nine months ended September 30, 2019 and 2018, respectively. We have incurred significant losses in each period since our inception in 2008, with net losses of $3.7 million and $6.7 million during the three months ended September 30, 2019 and 2018, respectively, and $18.8 million and $28.6 million during the nine months ended September 30, 2019 and 2018, respectively. We have not been profitable since inception, and as of September 30, 2019, our accumulated deficit was $167.5 million. From inception through September 30, 2019, we have

financed our operations primarily through private placements of our preferred stock, the sale of common stock in our IPO and in subsequent public and private placements, and, to a lesser extent, debt financing arrangements.

In August 2019, we issued and sold an aggregate of (i)2,427,500 shares of our common stock (including412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to1,735,000 shares of common stock ("Pre-funded Warrants"), (iii) accompanying warrants to purchase up to 3,234,375 shares of common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) ("Purchase Warrants") and (iv) an additional warrant to the underwriters for the purchase 37,500 shares of common stock ("Representative Warrant") resulting in net proceeds from the offering of approximately$14.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The offering was made pursuant to a registration statement on Form S-1. As of September 30, 2019, we had cash and cash equivalents of $19.4 million. During the second quarter of 2019, we paid down$15.0 million of the principal balance due under the loan and security agreement with Pacific Western Bank (as successor-in-interest to Square 1 Bank) and during the third quarter of 2019, the Company paid down the remaining $5.0 million of principal balance due under the loan and security agreement with Pacific Western Bank, thereby removing the risks and restrictions of carrying long-term debt.

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

Our consolidated financial statements as of and for the nine months ended September 30, 2019 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Based on our cash balances and recurring losses since inception, there is substantial doubt about our ability to continue as a going concern and if we are not able to continue to raise sufficient capital, we will not be able to support ongoing operations.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Revenue

For the three and nine months ended September 30, 2019 and 2018, revenue reflects sales of our Obalon Balloon System directly to physicians and institutions in the United States. For the nine months ended September 30, 2019, and the three and nine months ended September 30, 2018, revenue also reflects 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 to be our primary market. However, in the fourth quarter of 2019, we anticipate revenue from the discreet sale of product to an international distributor. In April 2019, we restructured operations and eliminated the field sales force, and transitioned to a centralized customer support model to support our physician customers. 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 Company-owned or managed retail treatment center model, our ability to develop the intragastric balloon market (which is currently small and immature), acceptance of our current Obalon Balloon System and its future iterations by doctors and patients, our ability to scale production in a cost effective manner, the emergence of competing products, actions by regulatory bodies and general economic trends. The amount of revenue and timing of revenue recognition may also be impacted by the customer incentive programs we decide to offer and the channels through which the revenue is derived.

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

Cost of revenue and gross margin

Cost of revenue consists primarily of costs related to the direct materials and direct labor that are used to manufacture our products and the overhead costs that directly support manufacturing. Currently, a significant portion of our cost of revenue consists of manufacturing overhead, which is mostly fixed in nature. These overhead costs include the costs of compensation for operations management, engineering support, material procurement and inventory control personnel, outside consultants, production related supplies, allocated quality assurance and facilities costs, and depreciation on production equipment. We expect cost of revenue to increase at a higher rate with U.S. commercialization of the Obalon Navigation System due to higher costs associated with capital equipment, including the Obalon Navigation System Console and Obalon Touch Inflation Dispenser, and inefficiencies associated with manufacturing scale up for our new Obalon Navigation balloon and related components. Longer term, we expect cost of revenue to increase in absolute dollars to the extent our revenue grows but decrease as a percentage of revenue over time as the fixed portion of our overhead costs is allocated over a greater number of units produced.

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

Research and development expenses

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

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

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

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

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, commissions, benefits, travel expense and stock-based compensation expense. Other SG&A expenses include promotional and advertising activities, marketing, conferences and trade shows, professional services fees, including legal fees, accounting fees, insurance costs, general corporate expenses, and allocated facilities-related expenses. SG&A expenses decreased in the third quarter of 2019 due to overall headcount reductions and elimination of significant one-time charges executed in the second quarter of 2019, but could increase in absolute dollars in subsequent quarters. SG&A expenses are expected to vary as a percentage of total revenue for the foreseeable future.

RESULTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)			
Condensed consolidated statements of operations data:				
Revenue	$ 333	$ 2,987	$ 2,494	$ 7,065
Cost of revenue	412	1,418	2,323	3,919
Gross (deficit) profit	(79)	1,569	171	3,146
Operating expenses:				
Research and development	1,174	2,368	5,401	8,359
Selling, general and administrative	2,489	5,836	13,025	23,092
Total operating expenses	3,663	8,204	18,426	31,451
Loss from operations	(3,742)	(6,635)	(18,255)	(28,305)
Interest income (expense), net	37	(70)	(448)	(164)
Other expense, net	(1)	(40)	(60)	(155)
Net loss	(3,706)	(6,745)	(18,763)	(28,624)
Other comprehensive income (loss)	—	(3)	—	3
Net loss and comprehensive loss	$ (3,706)	$ (6,748)	$ (18,763)	$ (28,621)

Comparison of three months ended September 30, 2019 and 2018

Revenue. Revenue decreased $2.7 million to $0.3 million during the three months ended September 30, 2019, compared to $3.0 million during the three months ended September 30, 2018. The revenue decrease was primarily due to a decrease of $1.2 million in sales to our Middle East distributor and a decrease of $1.5 million in U.S. sales, due to the decrease in total balloon units sold worldwide. The decrease in U.S. sales was largely attributable to the elimination of our direct field sales force in the second quarter of 2019 and our transition to a centralized customer support model.

Cost of revenue and gross profit. Cost of revenue decreased $1.0 million to $0.4 million during the three months ended September 30, 2019, compared to $1.4 million during the three months ended September 30, 2018. This was primarily attributable to the decrease in revenue compared to the prior year period. Gross deficit increased $1.6 million to $0.1 million during the three months ended September 30, 2019, compared to a gross profit of $1.5 million during the three months ended September 30, 2018. The increase in gross deficit was primarily attributable to the decrease in revenue compared to the prior year period, coupled with continued fixed operational expenses, such as indirect charges and facilities.

Research and development expenses. R&D expenses decreased $1.2 million to $1.2 million during the three months ended September 30, 2019, compared to $2.4 million during the three months ended September 30, 2018. This decrease was due primarily to decreases in payroll related expenses of $0.8 million, supplies expense of $0.2 million and stock-based compensation expense of $0.2 million resulting from a reduction in headcount associated with internal restructuring activities initiated in the second quarter and completed in the third quarter of 2019.

Selling, general and administrative expenses. SG&A expenses decreased $3.3 million to $2.5 million during the three months ended September 30, 2019, compared to $5.8 million during the three months ended September 30, 2018. The decrease from the prior period was primarily driven by a decrease of $1.8 million in payroll related expenses, travel expenses and stock-based compensation expense resulting from a reduction in headcount, a decrease of $1.2 million in spending on marketing and advertising programs and a decrease of $0.3 million in sales commissions.

Interest income (expense), net. Interest income, net changed from $70,000 of interest expense, net during thethree months ended September 30, 2018, to $37,000 of interest income, net during the three months ended September 30, 2019. The change was attributable to our repayment of $5.0 million in long term debt under our loan and security agreement with Pacific Western Bank coupled with interest income earned on $14.7 million of net proceeds from equity financing during the three months ended September 30, 2019.

Comparison of nine months ended September 30, 2019 and 2018

Revenue. Revenue decreased $4.6 million to $2.5 million during the nine months ended September 30, 2019, compared to $7.1 million during the nine months ended September 30, 2018. The revenue decrease was primarily due to a decrease of $2.6 million in sales to our Middle East distributor and a decrease of $2.0 million in U.S. sales, due to a decrease in total balloon units sold worldwide.

Cost of revenue and gross profit. Cost of revenue decreased $1.6 million to $2.3 million during the nine months ended September 30, 2019, compared to $3.9 million during the nine months ended September 30, 2018. This was primarily attributable to a decrease in revenue compared to the prior year period. Gross profit decreased $3.0 million to $0.2 million during the nine months ended September 30, 2019, compared with the nine months ended September 30, 2018. Gross profit as a percentage of revenue decreased to 7% during the nine months ended September 30, 2019, compared to 44% during the nine months ended September 30, 2018. This was primarily attributable to the decrease in revenue compared to the prior year period, coupled with the inventory write down in connection with the discontinuance of the prior generation Obalon Balloon System and the continued fixed operational expenses, such as indirect charges and facilities.

Research and development expenses. R&D expenses decreased $3.0 million to $5.4 million during the nine months ended September 30, 2019, compared to $8.4 million during the nine months ended September 30, 2018. This decrease was due primarily to decreases in payroll and travel related expenses of $1.7 million, supplies expense of $0.6 million, clinical trial expense of $0.4 million and stock-based compensation expense of $0.2 million. One-time restructuring charges of approximately $0.4 million reported in the second quarter are included in R&D expenses for the nine months ended September 30, 2019.

Selling, general and administrative expenses. SG&A expenses decreased $10.1 million to $13.0 million during the nine months ended September 30, 2019, compared to $23.1 million during the nine months ended September 30, 2018. The change from the prior period was primarily driven by a decrease of $5.3 million in payroll related expenses, travel expenses and stock-based compensation expense due to a reduction in headcount, a decrease of $3.9 million in spending on marketing and advertising programs and a decrease of $0.8 million in sales commissions. One-time restructuring charges of approximately $0.7 million reported in the second quarter are included in SG&A expenses for the nine months ended September 30, 2019.

Interest expense, net. Interest expense, net increased $0.3 million to $0.4 million during the nine months ended September 30, 2019, compared to $0.2 million during the nine months ended September 30, 2018. This increase was attributable to the $10.0 million draw down on the second tranche under our loan and security agreement with Pacific Western Bank for a total outstanding amount of $20.0 million in the first quarter of 2019, coupled with increase in the prime rate during the nine months ended September 30, 2019 compared to the prior year period. During the second and third quarters of 2019, we repaid the outstanding debt balance, thereby reducing overall interest expense. Interest income associated with $14.7 million in equity financing in August 2019 further reduced overall interest expense for the nine months ended September 30, 2019.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2019, we had cash and cash equivalents of $19.4 million and an accumulated deficit of $167.5 million. Our primary sources of capital have been private placements of preferred stock, the sale of common stock in our IPO and in subsequent public and private placements, and, to a lesser extent, the incurrence of debt.

In August 2019, we issued and sold an aggregate of (i) 2,427,500 shares of our common stock (including 412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of common stock ("Pre-funded Warrants"), (iii) accompanying warrants to purchase up to 3,234,375 shares of common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) ("Purchase Warrants") and (iv) an additional warrant to the underwriters for the purchase 37,500 shares of common stock ("Representative Warrant") resulting in net proceeds from the offering of approximately $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The offering was made pursuant to a registration statement on Form S-1. During the second quarter of 2019, we paid down $15.0 million of the principal balance due under the loan and security agreement with Pacific Western Bank (as successor-in-interest to Square 1 Bank). During the third quarter of 2019, we paid the remaining $5.0 million of principal balance due under the loan and security agreement with Pacific Western Bank, thereby removing the risks and restrictions of carrying long-term debt.

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

Public Offering

As noted above, on August 1, 2019, we entered into an underwriting agreement with A.G.P./Alliance Global Partners, as underwriter, in connection with a public offering of our securities, pursuant to which we issued and sold (i) 2,427,500 shares of our common stock (including 412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of our common stock ("Pre-funded Warrants"), (iii) accompanying warrants to purchase up to 3,234,375 shares of our common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) ("Purchase Warrants") and (iv) an additional warrant to the underwriters for the purchase of 37,500 shares of our common stock ("Representative Warrant") resulting in net proceeds from the offering of approximately $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The shares of common stock and accompanying Purchase Warrants were sold at a public offering price of $4.00, and the Pre-funded Warrants and accompanying Purchase Warrants were sold at a public offering price of $3.999. The Purchase Warrants were immediately exercisable upon issuance, will expire on August 6, 2024 and have an exercise price of $4.40 and the Representative Warrant has an exercise price of $5.00 per share, in each case subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events. The Representative Warrant is exercisable in February 2020 and expire on August 6, 2014. All of the Pre-funded warrants were exercised during the third quarter of 2019. None of the Purchase or Representative Warrant have been exercised as of September 30, 2019.

Securities Purchase Agreement

On May 23, 2019, we entered into a Securities Purchase Agreement with certain investors for the sale of 500,000 shares of our common stock, par value $0.001 per share, at a purchase price of $6.00 per share. The closing of the sale of the shares under the Securities Purchase Agreement occurred on May 28, 2019. The aggregate gross proceeds for the sale of the shares was $3.0 million.

Equity Distribution Agreement

On December 27, 2018, we entered into the Equity Distribution Agreement, with Canaccord, pursuant to which we may, from time to time, sell shares of our common stock, having an aggregate offering price of up to $10 million through Canaccord, as our sales agent. Any shares sold pursuant to the Equity Distribution Agreement will be freely tradeable unless purchased by one of our affiliates.

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

under our ATM program, is limited to an aggregate of one-third of our public float. As of September 30, 2019, the Company sold 377,615 shares under the Equity Distribution Agreement for aggregate gross proceeds of $2.8 million.

Lincoln Park Purchase Agreement

On December 27, 2018, we entered into a Purchase Agreement and Registration Rights Agreement, with Lincoln Park Capital Fund LLC, or Lincoln Park, pursuant to which we have the right, but not the obligation, to sell Lincoln Park, and Lincoln Park is obligated to purchase up to $20.0 million of our common stock, over the 36-month period that commenced in February 2019.

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

Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $20.0 million over the term of the Lincoln Park Purchase Agreement. For example, we cannot sell shares to Lincoln Park on any day in which the closing price of our common stock is below $0.50 per share. Our closing price has been below $0.50 per share for 11 of the last 30 trading days. Additionally, under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding (which is approximately 465,470 shares based on 2,328,512 shares outstanding prior to the signing of the Lincoln Park Purchase Agreement) under the Lincoln Park Purchase Agreement unless we obtain stockholder approval or an exception pursuant to the rules of the Nasdaq Capital Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the exchange cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Lincoln Park Purchase Agreement is equal to or greater than the specified minimum amount set forth in the Lincoln Park Purchase Agreement. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Capital Market. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Park's beneficial ownership exceeding 9.99% of the then outstanding shares of our common stock. Our inability to access a portion or the full amount available under the Lincoln Park Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business.

We issued to Lincoln Park 22,818 shares of common stock as commitment shares in consideration for entering into the purchase agreement. As of September 30, 2019, the Company has sold 356,122 shares under the Lincoln Park Purchase Agreement for aggregate gross proceeds of $4.2 million.

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

Additional Capital Requirements

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

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

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

CASH FLOWS

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

	Nine Months Ended September 30,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	$ (17,987)	$ (24,017)
Investing activities	2,506	14,332
Financing activities	13,674	10,129
Net (decrease) increase in cash and cash equivalents	$ (1,807)	$ 444

Net cash used in operating activities

During the nine months ended September 30, 2019, net cash used in operating activities was $18.0 million, consisting primarily of a net loss of $18.8 million, a decrease in net operating assets of $2.4 million primarily related to a decrease in accrued compensation, partially offset by a decrease in other current assets. These items were partially offset by non-cash charges of $3.2 million, consisting primarily of stock-based compensation expense and depreciation expense.

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.

Net cash provided by investing activities

During the nine months ended September 30, 2019, net cash provided by investing activities was $2.5 million, consisting primarily of maturities of short-term investments.

During the nine months ended September 30, 2018, net cash used in 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.

Net cash provided by financing activities

During the nine months ended September 30, 2019, net cash provided by financing activities was $13.7 million, consisting primarily of $23.7 million in proceeds from issuance of equity securities, net of issuance costs, the draw down on the second tranche under our loan and security agreement with Pacific Western Bank of $10.0 million, partially offset by the subsequent pay down on the loan with Pacific Western Bank of $20.0 million.

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 the 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 unconsolidated 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 842, under the heading "Leases," and "Recently Adopted Accounting Pronouncements," and "Variable Interest Entities", as discussed in Note 2 to our Unaudited Interim Condensed Consolidated Financial Statements, 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, 2018, filed on February 22, 2019.

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 lease accounting guidance found in ASC 842, there have been no new accounting pronouncements or changes to accounting pronouncements during the nine months ended September 30, 2019, as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed on February 22, 2019.

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

Not applicable.

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 has concluded that as of September 30, 2019, our disclosure controls and procedures were effective at the reasonable assurance level. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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, 2019 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 underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation.

On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims. We believe the remaining claims in the complaint are without merit and intend to defend vigorously against them.

ITEM 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

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to invest in a centralized customer support model, 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 general and administrative costs as a result of supporting growth and operating as a public company. The audit report of our independent registered public accounting firm covering the December 31, 2018 consolidated financial statements contains an explanatory paragraph that states that our recurring losses from operations and liquidity position raises substantial doubt about our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. To date, our operating losses have been funded primarily from outside sources of invested capital and gross profits. We currently need to raise additional cash from outside sources to fund our ongoing operations.

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

Historically we have sold our products directly to physicians, who then sold their patients treatment packages that include our balloon therapy, dietary counseling and removal on a non-reimbursed, self-pay basis. Beginning in April 2019, we eliminated approximately 50% of our workforce. As part of the workforce restructuring, we eliminated our field sales force and

transitioned to a more centralized customer support model. Going forward, rather than focusing on selling to physicians, we intend to focus our commercialization efforts on the establishment and operation of company-owned or managed Obalon-branded retail treatment centers. In the third quarter of 2019, we opened our first Obalon-branded retail treatment center in California, engaged a medical director, hired non-medical staff to support operations and initiated digital marketing programs to drive patient interest. Under this model, subject to state law and any federal requirements, we plan to either directly employ the physicians or contract for their services, and we will be directly responsible for marketing and patient acquisition. We would also provide the facilities, staff, equipment and support services necessary for patients to receive Obalon balloon therapy. Our intent with this strategic shift is to standardize both quality of care and patient pricing, and provide us greater operational and financial control of our business. While we have historically provided marketing services intended to drive patients to physician offices, we have no prior experience marketing our products to drive patients to our own centers and we cannot assure you that this new strategic model will be successful.

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

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

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

If we are unable to secure additional financing on favorable terms, or at all, to meet our current capital needs, we could be forced to sell portions of our business or seek bankruptcy protection to protect stakeholder value.

We recently initiated the transition of our commercialization efforts to focus on Obalon-branded or managed retail treatment centers. We have opened one such facility and expect that we will need significant additional capital to execute on this strategy. We may seek additional debt or equity financing in order to support our new operating plan. However, adequate funding may not be available to us on acceptable terms, or at all. The failure to obtain sufficient funds on acceptable terms or in a timely manner could force us to take actions that could materially and adversely affect our business, including further reductions in our operations (including our employee base), possible surrender or other disposition of our rights to some technologies or product opportunities, delaying the opening of any planned company-owned or managed Obalon-branded retail treatment center, delaying of our clinical trials or curtailing or ceasing operations and could result in us seeking bankruptcy protection. We also cannot give assurance that we will achieve sufficient revenues in the future to achieve profitability and cash flow positive operations to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause third parties including suppliers, customers, and employees to terminate their respective relationship with us due to concerns about our ability to meet our contractual obligations, which could have a material adverse effect on our business.

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

- the rate at which the currently small and immature intragastric balloon market develops;
- the degree of success we experience in commercializing our Obalon Balloon System with both the centralized customer support model and Obalon-branded or managed retail treatment centers;
- our ability to scale manufacturing in a cost-effective manner to meet demand;
- costs associated with opening and operating company-owned or managed Obalon-branded retail treatment centers;
- the costs and expenses of our U.S. sales and marketing infrastructure, operational expenses associated with Obalon-branded or managed retail treatment centers, and our manufacturing operations;
- the revenue and gross profit generated by sales of our Obalon Balloon System, Obalon Navigation System, and any other products that may be approved in the United States;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our products under development;
- the costs and timing of developing enhancements of our Obalon Balloon System and Obalon Navigation System and obtaining FDA clearance or approval of such enhancements;
- the emergence of competing or complementary technological developments;
- the extent to which our Obalon Balloon System and Obalon Navigation System are adopted by the physician community and patients;
- the number and types of future generation products we develop and commercialize and their success and adoption in the marketplace;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- costs of operating as a public company and compliance with existing and future regulations;
- the extent and scope of our general and administrative expenses;
- the legal costs associated with defending against shareholder litigation; and
- the degree of success we experience in international sales of our Obalon Balloon System.

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 the company-owned or managed Obalon-branded retail treatment centers, negatively impact services associated with our centralized customer support model, delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay other activities necessary to commercialize our products. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

We have implemented alternative financing arrangements including an "at-the-market" offering program and a purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Pursuant to the purchase agreement with Lincoln Park, or the Lincoln Park Purchase Agreement, Lincoln Park has committed to purchase up to $20.0 million of our common stock from time to time over a 36-month period that commenced on February 13, 2019. Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $20.0 million over the term of the Lincoln Park Purchase Agreement. Per terms of the agreement, we are not able to sell shares to Lincoln Park under the existing agreement if the closing price of our stock is below a specific minimum price. In addition, under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding under the Lincoln Park Purchase Agreement unless we obtain stockholder approval or an exception pursuant to the rules of the Nasdaq Capital Market is obtained to issue more than 19.99%. This limitation will not apply in certain limited circumstances as set out in the Lincoln

Park Purchase Agreement. As of September 30, 2019, we have sold 356,122 shares to Lincoln Park. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Global Market. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Park's beneficial ownership exceeding 9.99% of the then outstanding shares of our common stock. Our inability to access a portion or the full amount available under the Lincoln Park Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business.

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

We have a limited operating history and have focused primarily on research and development, clinical trials, product engineering and building our manufacturing capabilities. Before launching our prior generation Obalon Balloon System in the United States in January 2017, we sold an earlier generation of our product in certain international markets. Our commercial sales experience has been limited. We have incurred significant losses in each period since our inception in 2008, with net losses of $3.7 million and $6.7 million during the three months ended September 30, 2019 and 2018, respectively, and $18.8 million and $28.6 million during the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of approximately $167.5 million and had cash and cash equivalents of $19.4 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop, seek and obtain regulatory approval for our current and future generation Obalon Balloon System, sell our Obalon Balloon System in international markets, and commercialize our Obalon Balloon System in the United States. Our consolidated financial statements as of and for the six month period ended September 30, 2019 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Based on our cash balances and recurring losses since inception, there is substantial doubt about our ability to continue as a going concern and if we are not able to raise additional capital in a timely manner, we will not be able to support our ongoing operations.

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

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

We were incorporated in 2008, and prior to January 2017 our business activities were focused on the development and regulatory approval of our Obalon Balloon System and building the commercial infrastructure to sell our product in the United States. We commenced commercial launch of our prior generation Obalon balloon system in the United States in January 2017 and commenced commercial shipments of our most recent iteration of our Obalon Balloon System, Obalon Navigation System and Obalon Touch Inflation Dispenser in the United States in the first quarter of 2019. All of our revenue to date is attributable to sales of our Obalon Balloon System including its component parts and accessories. In the future, we expect to continue to generate sales of our products to physicians through a centralized customer support model and intend to establish a separate company-owned or managed Obalon-branded retail treatment center model. Through 2016, our primary commercial sales experience was limited to sales to distributors in a limited number of countries outside the United States. We expect that sales through our centralized customer support model to physicians in the United States will account for a majority of our revenue for the foreseeable future as we establish the company-owned or managed Obalon-branded retail treatment center business. However, we eliminated our direct sales force early in the second quarter of 2019 and anticipate that will significantly reduce revenue until we are able to grow our Obalon-branded or managed retail treatment centers. Our limited operating and commercialization experience in what we expect will be our primary market makes it difficult to evaluate our current business and predict our future prospects. Throughout 2019, we plan to phase out our prior generation Obalon balloon system that uses x-ray technology to place balloons, and eventually only sell versions of the Obalon Balloon System that use the Obalon Navigation System to place balloons. In the centralized customer support model for physicians, use of the Obalon Navigation System requires the physician to make a capital purchase of the Navigation console, Obalon Touch Dispenser, Obalon Navigation Balloon Kits and consumables and physicians are responsible for driving patient interest. We cannot assure you that

our current physician customers will be willing to make that purchase, and if we cannot transition physicians who currently use the prior generation Obalon balloon system to the Obalon Navigation System, we may experience a decline in sales. 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, whether at company-owned or managed Obalon-branded retail treatment centers or otherwise;
- the degree of success we experience in commercializing our Obalon Balloon System with both the centralized customer support model and company-owned or managed Obalon-branded retail treatment centers;
- 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;
- willingness of physicians to purchase the capital equipment required to place balloons using the Obalon Navigation System;
- any safety or efficacy concerns for the category of intragastric balloons, including liquid-filled balloons, as the FDA has issued three Letters to Health Care Providers warning them about the use of liquid-filled intragastric balloons citing potential risks, including death;
- changes in the composition of our customer base caused by acquisition of private medical practices by large hospitals could extend our selling cycle;
- our ability to develop, finance, obtain regulatory approval for, and successfully launch our next generation products and the success of our next generation products in the marketplace;
- our ability to develop, obtain regulatory approval for, and successfully manage the company-owned or managed Obalon-branded retail treatment center;
- our ability to service and maintain equipment such as the Obalon Navigation System;
- our ability to maintain our current or obtain further regulatory clearances, licenses or approvals;
- delays in, or failure of, product and component deliveries by our third-party suppliers and single-source suppliers;
- difficulties in producing a sufficient quantity of our product to meet commercial demand due to shortages of component parts or due to issues in the manufacturing process;
- introduction of new procedures or products for treating patients who are obese or overweight that compete with our product;
- adverse changes in the economy that reduce patient demand for elective procedures;
- performance of our international 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 are required to maintain high levels of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.

As a result of the need to maintain substantial levels of inventory due to single third-party sourcing and long lead-times to develop alternate third-party sources, we carry a high level of inventory for strategic materials and products and are subject to the risk of inventory obsolescence. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment

charges and costs required to replace such inventory. In addition, because we are a vertically integrated manufacturer, insufficient demand for our products may subject us to the risk of high inventory carrying costs and increased inventory obsolescence.

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

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

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

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

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 one other intragastric balloon available for sale in the United States, which was available starting in 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 patients and physicians, and successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our Obalon Balloon System. In April 2019, as part of a restructuring, we eliminated our direct field sales force and transitioned to a centralized customer support model for our existing physician customers and focused our efforts on establishing our first company-owned or managed Obalon-branded retail treatment center. We expect to continue investing in the various activities to develop the intragastric balloon market for the foreseeable future. Since we received PMA approval for the Obalon Balloon System in September 2016, we have engaged in various marketing campaigns 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. Though we recently eliminated our direct sales force, using our centralized customer support model, we continue to target our sales efforts towards bariatric surgeons and gastroenterologists, 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. If we experience physician disruption due to our shift to a centralized customer support model, we may experience a decrease in sales. Also, the initial point of contact for many patients who are obese and overweight may be general practitioners, bariatricians, endocrinologists, obstetricians and gynecologists, each of whom commonly manage and regularly see patients that are obese and overweight. If these physicians are not made aware of our Obalon Balloon System, they may not refer patients to bariatric surgeons, gastroenterologists or Obalon-owned or managed retail treatment centers 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 health care providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. We are aware of the filing of additional reports of serious adverse events, including deaths, associated with liquid-filled balloons since the issuance of the FDA safety alert letters. While the alerts were specific to liquid-filled intragastric balloons and not gas-filled intragastric balloons, these alerts could create negative perceptions of the entire category and slow down the acceptance of the Obalon Balloon System. Medical professional associations, such as ASMBS, have or may publish positions to their memberships which may be favorable or unfavorable toward the use of intragastric balloons, or the Obalon Balloon specifically. Additionally, if patients undergoing treatment with our Obalon Balloon System perceive the weight loss inadequate or adverse events too numerous or severe as compared with the treatment rates of alternative balloons or procedures, it will be difficult to demonstrate the value of our Obalon Balloon System to patients and physicians. As a result, demand for our Obalon balloon system may decline or may not increase at the pace or to the levels we expect.

If physicians do not choose to recommend the Obalon Balloon System 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 recommend it to their patients. Physicians may not prescribe our Obalon Balloon System unless they are able to determine long-term ability of Obalon to continue operations, and 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 endoscopy which is necessary to remove the Obalon Balloon System;
- reluctance to invest in ancillary equipment, such as the Obalon Navigation System, which is necessary to place an Obalon balloon;
- 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;
- lack of confidence in Obalon continuation of operations or ability to effectively shift to a centralized support model;
- perceived liability risk generally associated with the use of new products and procedures;
- lack or perceived lack of sufficient clinical evidence supporting clinical benefits;
- reluctance to change to or use new products;
- perceptions that our products are unproven or experimental;
- time and skill commitment that may be required to gain familiarity with a new system; and
- difficulty convincing physicians of the economic benefit of our product to their practice.

We are also aware of certain characteristics and features of our Obalon Balloon System that may prevent widespread market adoption. For example, for the Obalon Navigation System, a physician is required to purchase the capital component of the system, which is the console, to treat patients. Furthermore, 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 make the necessary financial and regulatory commitments and implement the appropriate practice management programs to successfully treat patients with the Obalon balloon, they may not adopt our balloon system.

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

We have limited experience as a company in the sales and marketing of our products. Prior to 2017, the majority of our product sales had been to a single international distributor in the Middle East. We first sold our products to physicians and institutions in the United States in 2017, and we commenced commercial shipments of our Obalon Navigation System in the first quarter of 2019. We anticipate the United States to be our primary market focus going forward. We recently eliminated our direct sales force and now sell to physicians through a centralized customer support model. In the centralized customer support model, marketing and clinical support is provided from our corporate office. Marketing support may include media assets and media purchasing support and leads generated from our Find-A-Doc locater. Training our applicable employees in use of our Obalon Balloon System and Obalon Navigation System to achieve the level of clinical competency expected by physicians, and to comply with applicable federal and state laws and regulations and our policies and procedures requires significant time, expense and attention. It can take several months to recruit and fully train employees. Our business may be harmed if there is excessive turnover in our employees that support our physician customers, or our efforts to train and retain our employees do not generate a corresponding increase in revenues. In particular, there is significant competition for qualified and experienced personnel. If we are unable to hire, develop and retain talented personnel or if new personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenues sufficiently to offset the cost incurred.

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

- the inability of our employees to perform their duties and conduct business in a manner that is compliant with our internal policies and procedures and FDA law and regulations;
- the inability of our employees to obtain access to an adequate numbers of physicians to recommend any current and future products;
- the lack of complementary products to be offered by our personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with our centralized customer support model, including the marketing organization;
- efforts by our competitors to commercialize products or procedures that address a similar patient population; and
- the existence of negative publicity about us or our products.

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

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

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 can occur and lead to serious injury requiring reporting 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. 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 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 have misused and ineffectively used our products for the treatment of patients. As a result, patients have experienced adverse events and have not been able to enjoy the benefits of our system or achieve the weight loss outcomes they expected, leading to dissatisfaction and could lead to market rejection of our products. Physicians may not follow our instructions for use when treating patients with our products. A physician's failure to follow our instructions for use or other 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 to prescribe the Obalon Balloon System. In our SMART pivotal trial, 7.6% of the combined treatment and control group patients failed to swallow a capsule with the microcatheter attached despite success swallowing a placebo that did not have a catheter attached. We are experiencing similar rates in U.S. commercial usage. There have also been instances where balloon deployment was negatively impacted due to a leak in the microcatheter caused by the patient biting the catheter during placement and requiring endoscopic removal. There may be other reasons for unsuccessful placements of which we are not yet aware. If the balloon is not successfully placed for any reason, the patient may attempt to seek a refund or monetary damages for the treatment. 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 serious injury related to the device or procedures as the result of the misuse or malfunction of, or design flaws in, our products, that could expose us to expensive litigation, divert management's attention and harm our reputation and business.

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

For instance, if the Obalon capsule does not reach a patient's stomach and is inflated in another portion of the body, such as the esophagus, the patient could experience a serious injury. A patient who experiences an esophageal inflation of the balloon would most likely require surgical intervention, and could die as a result of an esophageal inflation or as a result of complications from the subsequent intervention. Physicians may use the Obalon Navigation System to track the location of the balloon prior to inflation. Failure of the sensor to function or the Obalon Navigation System to dynamically track the capsule could result in serious injury if the Obalon balloon is inflated in another portion of the body, such as the esophagus. Perforation of the esophagus at any time, including during removal, is also possible. Esophageal perforation leading to sepsis and death associated with the sepsis has been reported with use of our product. Serious injury could also occur if one or more of the balloons deflates and migrates into the lower intestine causing an obstruction. This can also lead to surgical removal of the device and associated complications including death. Failure of the Obalon Touch Inflation Dispenser to function could result in need for immediate endoscopic removal or patient injury. Balloon deflation and migration into the lower intestine requiring surgical removal has also been reported with use of our product. Perforation of the stomach is also possible and can lead to surgical removal of the device and associated complications including death. Perforation of the stomach requiring surgical repair has also been reported with use of our product. One or more balloons may get lodged in the pyloric channel which could lead to severe dehydration and be life threatening and/or require surgical procedures to remove. Failure to transit has been

reported with use of our product and unscheduled endoscopy has been performed to remove the uninflated balloon. Aspiration during placement or removal is also a risk with intragastric balloons which could lead to pneumonia or other serious injury. Acute pancreatitis has been reported that may or may not be associated with the use of our product. While we have designed our products, and established instructions and protocols for physicians, to attempt to mitigate such risks, we cannot guarantee that adverse events will not occur again in the future. For example, physicians and/or patients have in the past failed, and may again in the future fail, to follow our instructions and protocols, and the safety systems we design into our products may not prevent all possible adverse events and injuries and/or our products may fail to function properly.

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

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

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

We do not expect that physicians or patients will receive third-party reimbursement for treatment using our products. As a result, we expect that our success will depend on the ability and willingness of 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. Additionally, we will need to demonstrate the ability to operate company-owned or managed Obalon-branded retail treatment centers successfully. Our centralized customer support 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 and Obalon Navigation System in commercial quantities and may experience production delays or issues in our manufacturing organization and be unable to meet current or future demand.

Prior to 2017, the majority of our product sales had been to a single international distributor in the Middle East. We first sold our products to physicians and institutions in the United States in 2017, and we anticipate the United States to be our primary market focus going forward. We have limited experience in manufacturing the current Obalon Balloon System, the Obalon Navigation System, and the Obalon Touch Inflation Dispenser in commercial quantities, and we will need to adjust our manufacturing capabilities in order to satisfy expected demand. We may find that we are unable to successfully manufacture these new products in sufficient quantities and expect manufacturing of the Obalon Navigation Balloon kit to be at a much higher per unit cost initially. We may need to adjust our manufacturing capabilities in order to satisfy expected demand for our Obalon Navigation balloon. In addition, the Obalon Navigation balloon with the Obalon Touch Inflation Dispenser utilizes a different catheter and dispenser configuration from our prior U.S. product, which we have limited experience manufacturing in commercial quantities.

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

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

- the reduction in workforce in April 2019 could negatively impact our ability to meet an increase in demand;
- the timing and process needed to assimilate the changes necessary to enable our production processes to accommodate anticipated demand;
- shortages that we may experience in any of the key components or sub-assemblies that we obtain from third-party suppliers;
- production delays or stoppages caused by receiving components or supplies which do not meet our quality specifications;
- delays that we may experience in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;
- delays that we may experience in seeking FDA review and approval of PMA supplements required for certain changes in manufacturing facilities, methods or quality control procedures;
- our limited experience in complying with the FDA's Quality System Regulation, or the QSR, which sets forth good manufacturing practice requirements for medical devices and applies to the manufacture of the components of our Obalon Balloon System;
- our ability to attract, train, and retain qualified employees, who are in short supply, in order to increase our manufacturing output;
- our ability to design and validate processes to allow us to manufacture future generations of the Obalon Balloon System that meets or exceeds our quality specifications in an efficient, cost-effective manner;
- our ability to produce commercial product that meets or exceeds our manufacturing specifications and release criteria;
- production delays or stoppages caused by malfunction of production equipment and/or malfunction of the electrical, plumbing, ventilation, or cooling systems supporting our manufacturing facility; and
- production stoppages and/or product scrap caused by positive tests for objectionable organisms on our products.

As we have scaled manufacturing, we have experienced challenges in our ability to meet commercial demand. While we have taken steps to address these challenges, we cannot assure you those steps will be sufficient or that additional challenges will not arise as we continue with the commercialization of our Obalon Balloon System and the recently commercialized Obalon Navigation System. If we continue to experience these challenges, our revenue could be impaired, our costs could increase,

market acceptance for our product could be harmed and our customers might instead purchase our competitors' products. Our inability to successfully manufacture components of our Obalon Balloon System in quantities sufficient to meet expected demand would materially harm our business.

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

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

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

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

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

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

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 0.0% and 39.4% of our total revenue for the three months ended September 30, 2019 and 2018, respectively, and 23.6% and 45.4% for the nine months ended September 30, 2019 and 2018, respectively. In the first quarter of 2019, we completed final shipments of the current generation product to Bader, and going forward we intend to focus our selling efforts on the United States. The significant reduction in revenue from Bader in 2019 has had a significant impact on our financial performance. The current agreement with Bader expires on December 31, 2019 and does not include the Obalon Navigation System. We are not automatically renewing the contract and, if we continued operations with Bader, we would have to negotiate a new agreement. Currently, we do not have regulatory approval for our Obalon Navigation System and Obalon Touch Inflation Dispenser in the Middle East. However, there are certain countries in the Middle East that allow importation of medical device products with United States FDA approval or clearance to meet local regulatory standards, including Qatar.

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

Marketing our Obalon Balloon System outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our longer-term product development and regulatory strategy, we may expand into other select international markets, but we do not currently intend to devote significant additional resources to market our Obalon Balloon System internationally. Our decision to market our product primarily in the United States in the near-term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our product internationally. We have not submitted to the Competent Authority for CE-marking of the Obalon Navigation System or Obalon Touch Inflation Dispenser. Furthermore, given recent changes to the CE-mark process which requires additional filings, CE Mark for the prior version of the Obalon Balloon System will not be renewed in May 2020. However, there are certain countries in the Middle East that allow importation of medical device products with United States FDA approval or clearance to meet local regulatory standards, including Qatar.

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

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

In the United States, our product competes with a variety of pharmaceuticals, surgical procedures and devices for the treatment of obese and overweight people. There are several competitors in the pharmaceutical segment including Vivus, Inc., Eisai Co., Ltd, Inc., AstraZeneca plc, and Allergan plc. Large competitors in the surgical segment for weight loss and obesity include Ethicon Inc. (subsidiary of Johnson & Johnson), Medtronic plc (formerly Covidien Ltd.), Apollo EndoSurgery, Inc., and ReShape LifeSciences (which acquired the Lap-Band from Apollo Endosurgery, Inc. and currently sells that device worldwide). In addition, we are aware of at least two FDA approved liquid-filled balloon devices for treating overweight people, including both the ReShape Duo Balloon and the ORBERA Balloon, both of which are now owned by Apollo EndoSurgery. Outside of the United States, Allurion Technologies, Inc. has developed a swallowable, passable liquid-filled intragastric balloon that has been approved for sale in Europe and the Middle East and completed enrollment in a U.S. clinical trial; and Spatz Medical has

also developed a liquid-filled intragastric balloon that has been approved for sale in Latin America and Europe and is currently engaged in a U.S. clinical trial. We also compete against ReShape LifeSciences' Maestro device, which is intended to create weight loss by vagal nerve stimulation and Aspire Bariatrics' ApireAssist device. Gelesis developed a hydrogel technology that is intended to expand in the stomach by absorbing water to create the feeling of satiety. Its Plenity device was recently cleared by FDA. BAROnova recently gained FDA PMA approval in the U.S. for its transpyloric shuttle, a non-surgical, non-pharmacologic device to induce weight loss by slowing gastric emptying. Additionally, we are aware of numerous companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, any of which, if approved, could compete with us in the future.

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

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

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

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

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

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

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

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Although we have entered into employment agreements with some of our executive officers and key employees, each of them may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. We recently promoted William Plovanic to Chief Executive Officer from his prior role of Chief Financial Officer and he will continue to serve as President. We also promoted Nooshin Hussainy to Chief Financial Officer from her prior role of Vice President Finance and Controller. Andrew Rasdal continues to serve as Executive Chair of the Board of Directors.

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

Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Diego area, 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 a relatively short operating history as a commercial company and a limited history as a commercial company selling in the United States. We recently restructured the organization and reduced the overall headcount by approximately 65% since December 31, 2018. Our growth plan includes development of a business model to develop and operate company-owned or managed Obalon-branded retail treatment centers. We have no experience in operating company-owned or managed retail treatment centers and in September 2019 opened our first Company-owned retail treatment center. We will need to develop a retail treatment center management system, and have hired administrative staff, and continue to develop the financial and management controls and information systems to support our Obalon-branded retail treatment center strategy. Navigating the contraction and expansion of our business to support future growth imposes significant additional responsibilities on management, including the need to identify, recruit, train and integrate additional employees and the need to design and implement efficient, scalable processes. In addition, both contraction and rapid growth will place a strain on our administrative personnel, information technology systems, manufacturing operations, and other operational infrastructure. We must successfully expand our employee base 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 business cycle in a cost-effective manner could have an adverse effect on our ability to

achieve our development and commercialization goals, which in turn could adversely impact our business and results of operations.

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 and the Obalon Navigation System may in the future be subject to product recalls that could harm our reputation and business.

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

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

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

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

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

We also may be subject to claims against us due to actions of others. We rely on physicians in connection with the placement and subsequent removal of our Obalon balloon at the end of the six-month treatment period. 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 therapy. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and raw materials. This risk exists even if a device or product is cleared or approved for commercial sale by the FDA or other foreign regulators and manufactured in facilities registered with and regulated by the FDA or an applicable foreign regulatory authority.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- physicians and patients may be dissatisfied, seek refunds and refuse to use our products;
- we could be sued and held liable for injury caused to individuals using our product; and
- our reputation may suffer.

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

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

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

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

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

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

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

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

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory, product development tasks, quality assurance, clinical data, and customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or other catastrophic events. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Numerous and evolving cybersecurity threats pose potential risks to the security of our information technology systems, networks and products, as well as the confidentiality and integrity of our data. A security breach could impact the use of such products and the security of information stored therein.

The failure of our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages. For example, the loss of clinical trial data from completed or ongoing

clinical trials could result in delays in our regulatory efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could also incur liability. Any of these events could have a material adverse effect on our reputation, business, financial condition and results of operations.

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

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

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

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

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

We 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 restructuring announced in April 2019, which included the elimination of the field sales force and the June 2019 offer of voluntary separation packages to certain employees, could have a negative impact on our customers' perception and negatively impact our ability to collect amounts due from customers. 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.

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

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

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

At December 31, 2018, we had federal and state net operating loss carryforwards, or NOLs, of approximately $122.2 million and $87.9 million, respectively. The federal and state tax loss carryforwards will begin expiring in 2028, unless previously

utilized. The federal net operating loss carryover includes $34.0 million in net operating losses generated in 2018. Federal net operating losses generated in 2018 carryover indefinitely and may be generally used to offset up to 80% of future taxable income. We also had federal and California research and development tax credit carryforwards totaling $3.0 million and $2.4 million, respectively. The federal research and development tax credit carryforward will begin to expire in 2028 unless previously utilized. The California research tax credits do not expire.

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

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

RISKS RELATED TO REGULATORY MATTERS

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

Our Obalon Balloon System and Obalon Navigation System are medical devices that are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. We will be required to timely file various reports with the FDA, including reports required by the medical device reporting regulations, or MDRs, that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

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

In addition, as a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. For example, as part of our PMA approval, we are required to conduct a post-approval study at up to 16 sites in the United States to evaluate the safety and efficacy of our Obalon Balloon System in 200 subjects over a twelve-month period, consisting of six months of treatment with the Obalon Balloon System followed by six months of observation after balloon removal. We began patient enrollment in the post approval study in the second quarter of 2018 and in April 2019 we notified the FDA that we had temporarily paused active new patient enrollment to conserve cash resources and ensure we could meet future financial obligations to physicians and patients. We have subsequently notified the FDA in July 2019 that we have restarted enrollment. The FDA has approved this request. Failure to conduct post-approval studies in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would materially harm our business. As part of our PMA-S approval of the Obalon Navigation System, we are required to conduct a post-approval study at up to 40 sites in the United States to evaluate the safety and efficacy of our Obalon Navigation System for approximately 4,000 balloon placements, as it relates to the safety and efficacy of acute balloon placement including deployment, but not long-term results such as weight loss. We anticipate patient enrollment to begin in 2019. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data, when post-approval study data become available. Failure to conduct post-approval studies in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would materially harm our business.

If we initiate a correction or removal for one of our devices, issue a safety alert, or undertake a field action or recall to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device

recall, which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases, or administrative or judicial enforcement actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

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

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

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

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

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

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

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FFDCA. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. These proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could increase the costs of compliance, or otherwise create competition that may negatively affect our business. If we are slow or unable to adapt to changes in existing requirements or

the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

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

Once a medical device is approved, a manufacturer must notify the FDA of any modifications to the device. Any modification to a device that has received FDA approval that affects its safety or effectiveness requires approval from the FDA pursuant to a PMA supplement. An applicant may make a change in a device approved through a PMA without submitting a PMA supplement if the change does not affect the safety and effectiveness of the device and the change is reported to FDA in a post-approval periodic report required as a condition of approval. We may not be able to obtain additional premarket approvals for new products or obtain approval of PMA supplements for modifications to, or additional indications for, our Obalon Balloon System in a timely fashion, or at all. Delays in obtaining required future approvals would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. If we make additional modifications in the future that we believe do not or will not require additional approvals and the FDA disagrees and requires new approvals for the modifications, we may be required to recall and to stop selling or marketing our Obalon Balloon System as modified, which could harm our operating results and require us to redesign our Obalon Balloon System and Obalon Navigation System. In these circumstances, we may be subject to significant enforcement actions.

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

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

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

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

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

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

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

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

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

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

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

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

In the United States, before we can market a new medical device, or label and market a previously cleared or approved device for a new intended use or new indication for use, or make a significant modification to a previously cleared or approved device, we must first receive either FDA clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or approval of a PMA application from the FDA, unless an exemption applies. The process of obtaining PMA approval, which was required for the Obalon Balloon System, is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on

the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk.

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

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

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

Further, the FDA and European regulatory authorities strictly regulate the indications for use and associated promotional safety and effectiveness claims, including comparative and superiority claims vis a vis competitors' products, that may be made about products, such as the Obalon Balloon System. In particular, a medical device may not be promoted for uses or indications that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. For example, we will not be able to promote or make claims for the Obalon Balloon System for the treatment of patients outside of the BMI ranges specifically approved by the FDA or other regulatory authorities. In the United States, we received FDA approval of the Obalon balloon system for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40) who have failed to lose weight through diet and exercise. The Obalon Balloon System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed. Our pivotal trial inclusion and exclusion criteria included patients with a BMI of 30 to 40; thus, our approved labeling is limited to the same BMI range. We also will not be able to make comparative or superiority claims for the Obalon Balloon System versus other products without scientific data supporting or establishing those claims, including possibly data from head-to-head clinical trials if appropriate. Our CE mark label includes patients with a BMI of 27 or greater. As a part of our PMA approval, we are required to conduct a post-approval study at up to 16 sites in the United States to evaluate the safety and efficacy of our Obalon Balloon System over a twelve-month period, consisting of six months of treatment with the Obalon Balloon System followed by six months of observation after balloon removal. We began patient enrollment in the post-approval study in the second quarter of 2018 and in April 2019 we notified the FDA that we had temporarily paused active new patient enrollment to conserve cash resources and ensure we could meet future financial obligations to physicians and patients. The FDA has

approved this request. We have since notified the FDA that we have resumed enrollment. Failure to conduct post-approval studies in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would materially harm our business. As part of our PMA-S approval of the Obalon Navigation System, we are required to conduct a post-approval study of up to 40 sites in the United States to evaluate the safety and efficacy of our Obalon Navigation System as it relates to acute balloon placement including deployment. We anticipate patient enrollment to begin in 2019. The FDA has not approved this protocol such that this study can be initiated. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies, obtaining results different than our pivotal trial results or failure to comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or cleared or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

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

- ***Corporate Practice of Medicine.*** Some states have enacted laws and regulations limiting the extent to which physicians and certain other healthcare professionals may be employed by non-physicians or general business corporations. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. The scope and provisions of **c**orporate practice of medicines laws and regulations vary among the states. Violations may result in civil or criminal penalties.

- ***Other Healthcare Fraud Laws.*** HIPAA includes criminal health care fraud provisions and related rules that prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing or covering up a material fact or making any material false, fictitious or fraudulent statement in connection with the

delivery of or payment for healthcare benefits, items, or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- ***Transparency Laws.*** There has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals and entities. For example, the Physician Payment Sunshine Act, imposes annual reporting requirements on certain manufacturers of drugs, medical devices, biologics and medical supplies with respect to payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as with respect to certain ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information regarding all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on medical device manufacturers' marketing practices, require reporting of marketing and pricing information, and require the tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities under certain circumstances.

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

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

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

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

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

Federal, state, and local laws and policies impose various registration, accreditation, permit and/or licensing requirements on healthcare facilities and subject healthcare facilities to regulations ranging from the adequacy of medical care, to compliance with building codes and environmental protection laws. Additionally, physicians at our retail treatment centers, once operational, will also be subject to various state and federal regulations, including utilization of diagnostic tests and regarding

prescribing medication and controlled substances. Delays or failures to obtain or maintain any required registrations, accreditations, permits and other licenses could adversely impact our ability to establish and operate our retail treatment centers.

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

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

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

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 our Company-owned or managed treatment centers are required to be HIPPA compliant and have created the policies, procedures and completed training as required. We do not believe our corporate offices are required to be HIPPA compliant, but are nevertheless committed to maintaining the security and privacy of patients' health information. Violation of HIPAA could result in the imposition of civil or criminal penalties.

Numerous other federal and state laws may apply that restrict the use and protect the privacy and security of PII, including health information. These include state medical privacy laws, state social security number protection laws, state breach notification laws, and federal and state consumer protection laws. These various laws in many cases are not preempted by HIPAA and may be subject to varying interpretations by the courts and government agencies.

Noncompliance or findings of noncompliance with applicable laws, regulations or requirements, or the occurrence of any privacy or security breach involving the misappropriation, loss or other unauthorized disclosure of sensitive personal information, whether by us or by one of our third party service providers, could have a material adverse effect on our reputation and business, including, among other consequences, mandatory disclosure to the media, loss of existing or new patients, significant increases in the cost of managing and remediating privacy or security incidents and material fines, penalties and litigation awards, any of which could have a material adverse effect on our business, results of operations, and financial condition.

Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. We expect that there will continue to be new proposed laws, regulations and industry standards concerning privacy, data protection and information security in the United States, including the California Consumer Privacy Act, which will go into effect January 1, 2020, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, including health data, along with increased patient demands for enhanced data security infrastructure, could greatly increase our cost of providing our services, decrease demand for our services, reduce our revenue and/or subject us to additional liabilities.

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

As of September 30, 2019, we held 23 issued U.S. patents and had 19 pending U.S. patent applications, as well as 32 international patents issued in regions including Europe, Mexico, Australia, Canada, Asia, China and Israel and 54 pending international patent applications in regions including Australia, Canada, Europe, Asia, the Middle East and South America. Our issued patents expire between the years 2023 and 2038, and are directed to various features and combinations of features of the Obalon Balloon System technology, including the apparatus for connecting the balloon to an inflation catheter, the structure and composition of the balloon wall, and the composition of the initial fill gas.

As of September 30, 2019, we held two registered U.S. trademarks and 38 registered marks in Europe, the Middle East, Asia and Mexico. We have five pending U.S. trademark applications and three pending marks outside the United States, including in Europe, the Middle East, Asia and Mexico.

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

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

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect the Obalon Balloon System or any other products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our Obalon Balloon System before our relevant patents expire;
- we were the first to make the inventions shown in each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;

- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- that our commercial activities or products will not infringe the patents of others.

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

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

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

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. For example, each of our patents and patent applications names one or more inventors having past or present affiliations with other institutions, and any of these institutions may assert an ownership claim. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may infringe or be alleged to infringe the intellectual property rights of others, which may result in costly and time-consuming litigation, delay our product development efforts or prevent us from commercializing the Obalon Balloon System.

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

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

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and can have an uncertain outcome. Any claim relating to intellectual property infringement that is successfully asserted against us may require

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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, particularly in light of the current transition in our commercialization efforts;
- 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 and maintain NASDAQ minimum listing requirements; and
- developments in our industry.

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

If we fail to meet all applicable Nasdaq Global Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

On May 15, 2019, we received a written notification from Nasdaq notifying us that we are not in compliance with Nasdaq Listing Rule 5450(b)(1)(A) based on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, which reported our stockholders' equity as $6,518,000, which is below the minimum of $10,000,000 in stockholders' equity required for continued listing. In accordance with such notice, we submitted our plan to regain compliance with the minimum stockholders' equity requirement to Nasdaq on June 28, 2019. On July 10, 2019, the Staff notified us that it has determined to grant us an extension until November 11, 2019 to regain compliance. Under the terms of the extension, we must regain compliance with the minimum stockholders' equity requirement no later than November 11, 2019, provide to the Staff a publicly available report that evidences such compliance and otherwise comply with conditions included in the extension notice.

On May 16, 2019, we received a second written notification from Nasdaq notifying us that the closing bid price for our common stock had been below $1.00 for the last 30 consecutive business days and that we are not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Global Market under Nasdaq Listing Rule 5450(a)(1). Under the Nasdaq Listing Rules, we have a period of 180 calendar days from the date of this second notice, or until November 12, 2019, to regain compliance with the minimum bid requirement. To regain compliance, the closing bid price of our common stock must be at least $1.00 for a minimum of ten consecutive business days. In an effort to satisfy this requirement, we included, and our stockholders approved, a proposal in the proxy statement relating to our 2019 annual meeting of stockholders that allowed our board of directors to implement a reverse stock split at a ratio within the range of 1-for-5 to 1-for-20, of which a ratio of 1-for-10 was approved and effected.

Additionally, we conducted the following capital-raising transactions since the end of the quarter ended March 31, 2019; issued and sold $2.9 million in shares of our common stock in May 2019 and June 2019 pursuant to a purchase agreement with Lincoln Park Capital Fund, LLC; issued and sold $2.9 million in shares of our common stock in May 2019 and June 2019 pursuant to our equity distribution agreement with Canaccord Genuity LLC; issued and sold $3.0 million in shares of our common stock to investors in a registered direct offering in May 2019; and issued and sold shares of our common stock, pre-funded warrants and purchase warrants in August 2019 for net proceeds of approximately $14.7 million, after deducting underwriting discounts and commissions and expenses payable by the Company.

On October 1, 2019, we received notification from Nasdaq that we are in compliance with the minimum bid requirement. Additionally, as of September 30, 2019, we have increased our stockholders' equity and are now in compliance with the minimum stockholders' equity requirement. Nasdaq will continue to monitor our ongoing compliance with the minimum stockholders' equity requirement and, if at the time of our next periodic report we do not evidence compliance, we may be subject to delisting. There can be no assurance that we will maintain compliance with the minimum stockholders' equity requirement or will otherwise be in compliance with other Nasdaq listing rules.

In the event that our common stock is delisted from the Nasdaq Global Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

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

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

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

We will need additional capital in the future to continue our planned operations. Our alternative financing arrangements include an "at-the-market" offering program and the Lincoln Park Purchase Agreement. Upon execution of the Lincoln Park Purchase Agreement, we issued 22,818 commitment shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock. The remaining shares of our common stock that may be issued under the Lincoln Park Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period that commenced in February 2019. The purchase price for the shares that we may sell to Lincoln Park under the Lincoln Park Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall. To raise capital, we may utilize our alternative financing arrangements, 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, the anticipation of such 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 and investors that purchased shares in our private placement 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 options or warrants, 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 $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;

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

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

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

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

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

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

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

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

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

As of September 30, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 15% of our outstanding capital stock. This group of stockholders will likely have the ability to effectively control us through this ownership position. These stockholders may be able to significantly influence the outcome of any matter 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 Securities Exchange Act of 1934, as amended, or the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of the Company's initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation.

On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims. We believe the remaining claims in the complaint are without merit and intend to defend vigorously against them.

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

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

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

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

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

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

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

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

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

We have never declared or paid any cash dividends on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. 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

None.

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	Exhibit	File No.	Exhibit Filing Date	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation	S-1/A	3.2	333-213551	9/26/2016	
3.2	Certificate of Amendment to the Restated Certificate of Incorporation	8-K	3.1	001-37897	6/14/2018	
3.3	Amended and Restated Bylaws	S-1/A	3.4	333-213551	9/26/2016	
4.1	Form of Pre-Funded Warrant	S-1/A	4.5	333-232276	8/01/2019	
4.2	Form of Common Stock Purchase Warrant	S-1/A	4.6	333-232276	8/01/2019	
4.3	Form of Representative's Warrant	S-1/A	4.7	333-232276	8/01/2019	
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a) and15d-14(a), of the Securities and Exchange Act 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) and 15d-14(a) of the Securities and Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1†	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley 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 8, 2019 by: /s/ William Plovanic

William Plovanic
President & Chief Executive Officer

OBALON THERAPEUTICS, INC.

Date: November 8, 2019 by: /s/ Nooshin Hussainy

Nooshin Hussainy
Chief Financial Officer

Exhibit 31.1

OBALON THERAPEUTICS, INC.
CERTIFICATION OF PRESIDENT AND CHIEF EXECUTIVE 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 8, 2019

/s/ William Plovanic

William Plovanic
President and 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, Nooshin Hussainy, 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 8, 2019

/s/ Nooshin Hussainy

Nooshin Hussainy
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO SECTION 906

OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Obalon Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), William Plovanic, President and Chief Executive Officer of the Company, and Nooshin Hussainy, Chief Financial Officer of the Company, 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 or her knowledge:

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

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

Dated: November 8, 2019

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

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