
**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, 2016

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
(State of Incorporation)

**5421 Avenida Encinas, Suite F
Carlsbad, California**
(Address of Principal Executive Offices)

26-1828101
(I.R.S. Employer
Identification No.)

92008
(Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

Total shares of common stock outstanding as of the close of business on November 7, 2016:

Class	Number of Shares Outstanding
Common Stock, \$0.001 par value	16,772,818

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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, 2016	December 31, 2015
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,324	\$ 3,356
Short-term investments	11,829	9,175
Accounts receivable, related party	515	636
Inventory	438	363
Other current assets	2,857	273
Total current assets	17,963	13,803
Property and equipment, net	535	418
Total assets	\$ 18,498	\$ 14,221
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,068	\$ 549
Accrued compensation	684	1,250
Accrued clinical expenses	139	913
Other current liabilities	2,434	493
Customer deposit from related party	—	1,283
Current portion of long-term loan	—	747
Warrant liability	882	332
Total current liabilities	5,207	5,567
Long-term loan, excluding current portion	9,886	9,094
Total liabilities	15,093	14,661
Commitments and contingencies (See Note 10)		
Convertible preferred stock		
Series A convertible preferred stock, \$0.001 par value; 2,333,332 shares authorized; 804,595 shares issued and outstanding as of September 30, 2016 and December 31, 2015; liquidation preference of \$7,000 as of September 30, 2016 and December 31, 2015	6,773	6,773
Series B convertible preferred stock, \$0.001 par value; 4,333,332 shares authorized; 1,494,248 shares issued and outstanding as of September 30, 2016 and December 31, 2015; liquidation preference of \$6,500 as of September 30, 2016 and December 31, 2015	6,454	6,454
Series C convertible preferred stock, \$0.001 par value; 7,809,006 and 7,809,939 shares authorized as of September 30, 2016 and December 31, 2015, respectively; 2,668,533 shares issued and outstanding as of September 30, 2016 and December 31, 2015; liquidation preference of \$16,523 as of September 30, 2016 and December 31, 2015	16,393	16,393
Series C-1 convertible preferred stock, \$0.001 par value; 1,418,042 and 2,783,334 shares authorized as of September 30, 2016 and December 31, 2015, respectively; 480,286 shares issued and outstanding as of September 30, 2016 and December 31, 2015; liquidation preference of \$5,000 as of September 30, 2016 and December 31, 2015	4,984	4,984
Series D convertible preferred stock, \$0.001 par value; 8,076,436 and 11,546,013 shares authorized as of September 30, 2016 and December 31, 2015, respectively; 2,732,552 shares issued and outstanding as of September 30, 2016 and December 31, 2015; liquidation preference of \$20,590 and \$41,180 as of September 30, 2016 and December 31, 2015, respectively	20,095	20,095
Series E convertible preferred stock, \$0.001 par value; 10,490,611 and 0 shares authorized as of September 30, 2016 and December 31, 2015, respectively; 1,916,425 and 0 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively; liquidation preference of \$15,893 and \$0 as of September 30, 2016 and December 31, 2015, respectively	15,799	—
	70,498	54,699
Stockholders' deficit:		
Common stock, \$0.001 par value; 45,000,000 and 35,000,000 shares authorized as of September 30, 2016 and December 31, 2015, respectively; 1,383,624 and 575,126 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	1	1
Additional paid-in capital	2,015	1,002
Other comprehensive income	5	—
Accumulated deficit	(69,114)	(56,142)
Total stockholders' deficit	(67,093)	(55,139)
Total liabilities and stockholders' deficit	\$ 18,498	\$ 14,221

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,	
	2016	2015	2016	2015
	(Unaudited)			
Revenue:				
Revenue	\$ —	\$ —	\$ —	\$ 224
Revenue, related party	773	1,093	2,621	2,832
Total revenue	773	1,093	2,621	3,056
Cost of revenue	644	644	1,938	1,849
Gross profit	129	449	683	1,207
Operating expenses:				
Research and development	2,169	3,201	7,267	9,169
Selling, general and administrative	2,412	618	5,387	2,297
Total operating expenses	4,581	3,819	12,654	11,466
Loss from operations	(4,452)	(3,370)	(11,971)	(10,259)
Interest expense, net	(135)	(142)	(425)	(405)
Loss from change in fair value of warrant liability	(669)	(42)	(550)	(31)
Other expense, net	(4)	(8)	(26)	(24)
Net loss	(5,260)	(3,562)	(12,972)	(10,719)
Other comprehensive income (loss)	1	(2)	5	8
Net loss and comprehensive loss	\$ (5,259)	\$ (3,564)	\$ (12,967)	\$ (10,711)
Net loss per share, basic and diluted	\$ (5.46)	\$ (6.21)	\$ (18.36)	\$ (18.71)
Weighted-average common shares outstanding, basic and diluted	963,724	574,044	706,688	572,818

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
	(Unaudited)	
Operating activities:		
Net loss	\$ (12,972)	\$ (10,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	142	124
Stock-based compensation	200	153
Loss on disposal of fixed assets	13	2
Change in fair value of warrant liability	550	31
Amortization of investment premium, net	96	215
Amortization of debt discount	60	57
Change in operating assets and liabilities:		
Accounts receivable, net	—	97
Accounts receivable from related party	121	(542)
Inventory	(75)	103
Other current assets	(2,597)	(39)
Accounts payable and accrued expenses	519	268
Accrued compensation	(566)	(33)
Accrued clinical expenses	(774)	1,623
Other current liabilities	1,690	202
Customer deposit from related party	—	1,283
Net cash used in operating activities	(13,593)	(7,175)
Investing activities:		
Purchases of short-term investments	(18,897)	(14,238)
Maturities of short-term investments	16,150	11,200
Purchase of property and equipment	(259)	(83)
Net cash used in investing activities	(3,006)	(3,121)
Financing activities:		
Issuance of preferred stock for cash, net of offering costs	14,517	—
Proceeds from long-term loan, net of issuance costs	—	5,000
Fees paid in connection with loan amendment	(15)	—
Sale of common stock	1,065	61
Net cash provided by financing activities	15,567	5,061
Effect of exchange rate changed on cash and cash equivalents	—	3
Net decrease in cash and cash equivalents	(1,032)	(5,232)
Cash and cash equivalents at beginning of period	3,356	6,902
Cash and cash equivalents at end of period	\$ 2,324	\$ 1,670
Supplemental cash flow information:		
Interest paid	\$ 405	\$ 371
Non-cash investing and financing activities:		
Conversion of customer deposit from related party to preferred stock	\$ 1,283	\$ —

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 commercial-stage medical device company focused on developing and commercializing innovative medical devices to treat obese and overweight people. Using its patented technology, the Company has developed the Obalon balloon system, the first and only FDA approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients.

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

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

As of September 30, 2016, the Company has devoted a substantial portion of its efforts to product development, raising capital, and building infrastructure. The Company has incurred operating losses and has experienced negative cash flows from operations since its inception. In July 2012, the Company realized initial revenue from its planned principal operations. The Company recognized revenue, including revenue from related parties, of \$2.6 and \$3.1 million for the nine months ended September 30, 2016 and 2015, respectively. However, the Company has not yet established an ongoing source of revenues sufficient to cover its operating costs and has funded its activities to date almost exclusively from debt and equity financings. On September 8, 2016, the Company received premarket approval from the U.S. Food and Drug Administration, or FDA, to market the Obalon balloon system for temporary use to facilitate weight loss in obese adults with a body mass index, or BMI of 30 to 40 who have failed to lose weight through diet and exercise. The Obalon balloon system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. For all periods presented, all sales are to customers outside of the United States.

Initial Public Offering

On October 5, 2016, the Company's Registration Statement on Form S-1/A (File No. 333-213551) relating to the initial public offering, or IPO, of its common stock was declared effective by the Securities and Exchange Commission, or SEC. Pursuant to such Registration Statement, the Company sold an aggregate of 5,000,000 shares of its common stock at a price of \$15.00 per share for aggregate cash proceeds of approximately \$67.4 million, net of underwriting discounts, commissions, and estimated offering costs. The sale of 5,000,000 shares in the IPO closed on October 12, 2016.

On October 12, 2016, immediately prior to the closing of the IPO, all outstanding shares of convertible preferred stock converted into 10,360,419 shares of common stock and 12,217 shares of common stock were issued upon the automatic net exercise of two warrants.

September 2016 Reverse Stock Split

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

Liquidity

As reflected in the accompanying 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, 2016, its accumulated deficit was \$69.1 million. Since inception, the Company has financed its operations primarily through private placements of preferred securities and, to a lesser extent, debt financing arrangements. The Company expects to continue to incur net losses for the foreseeable future as it builds its sales and marketing organization, prepares for and proceeds to commercialization of its product in the United States and continues research and development efforts. The Company may need additional funding to pay expenses relating to its operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding, if needed, may not be available to the Company on acceptable terms, or at all. The failure to obtain sufficient funds on acceptable terms could have a material adverse effect on the Company's business, results of operations or financial condition.

2. Summary of Significant Accounting Policies

There were no significant changes to the accounting policies during the nine months ended September 30, 2016, from the significant accounting policies described in Note 2 of the “Notes to Consolidated Financial Statements” in the Prospectus dated and filed with the SEC on September 26, 2016, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or Prospectus.

Use of Estimates

The preparation of financial statements in conformity with Generally Accepted Accounting Principles, or 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. On an ongoing basis, management evaluates its estimates, including those related to the warrant liability, stock-based compensation, and income tax uncertainties.

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

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated financial statements as of September 30, 2016 and for the nine months ended September 30, 2016 and 2015 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, 2016 and its consolidated results of operations and cash flows for the nine months ended September 30, 2016 and 2015. The financial data and other information disclosed in these notes to the condensed consolidated financial statements related to the nine-month periods are also unaudited. The results of operations for the nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other future annual or interim period. The balance sheet as of December 31, 2015 included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company’s audited financial statements included in the Prospectus dated October 5, 2016, filed with the SEC on October 6, 2016 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus.

Short-Term Investments

The Company classifies its investments as available-for-sale and records such assets at estimated fair value in the balance sheet, with unrealized gains and losses, if any, reported as a component of other comprehensive loss within the consolidated statements of operations and comprehensive loss. All of the Company’s short-term investments are U.S. Treasury notes with maturities of less than one year. For the three and nine months ended September 30, 2016 and 2015, unrealized losses were immaterial. Realized gains and losses would be calculated on the specific-identification method and recorded as interest income (expense). There have been no material realized gains and losses for the three and nine months ended September 30, 2016 or 2015. The Company periodically reviews available-for-sale securities for other-than-temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable.

Fair Value Measurements

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

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

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

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to the IPO, are capitalized. The deferred offering costs will be offset against the IPO proceeds upon the consummation of the offering, which occurred on October 5, 2016. As of September 30, 2016, \$2.4 million of deferred offering costs have been incurred, which are included in other current assets in the accompanying condensed consolidated balance sheet. No deferred offering costs were capitalized as of December 31, 2015.

Net Loss per Share

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

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. Entities are able to use one of three prescribed transition methods. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. ASU 2014-09 is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2017.

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

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

In February 2016, the FASB issued ASU 2016-02, *Leases*. Under this new guidance, at the commencement date, lessees will be required to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. This guidance is not applicable for leases with a term of 12 months or less. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies the guidance in ASU No. 2014-09 when evaluating when another party, along with the entity, is involved in providing a good or service to a customer. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies the guidance in ASU No. 2014-09 regarding assessing whether promises to transfer goods or services are distinct, and whether an entity's promise to grant a license provides a customer with a right to use, or right to access the entity's intellectual property. In May 2016, the FASB issued ASU 2016-12 "Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients (Topic 606)", which clarifies the guidance on assessing collectability, presenting sales taxes, measuring noncash consideration, and certain transition matters. All standards are effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2017, and interim periods within that reporting period. The Company is currently evaluating the impact of the amended revenue recognition standard on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which involves several aspects of the accounting for stock-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This new guidance will require all income tax effects of awards to be recognized as income tax expense or benefit in the income statement when the awards vest or are settled, as opposed to additional paid-in-capital where it is currently recorded. It also will allow an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting. All tax-related cash flows resulting from stock-based payments are to be reported as operating activities on the statement of cash flows. The guidance also allows a Company to make a policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. This new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements.

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

3. Fair Value Measurements

Instruments Recorded at Fair Value on a Recurring Basis

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

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

		Fair value measurements at reporting date using		
	Balance as of September 30, 2016	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash and cash equivalents:				
Money market funds(1)	\$ 2,049	\$ 2,049	\$ —	\$ —
Short-term investments:				
U.S. Treasury bonds(2)	11,829	11,829	—	—
Total assets	<u>\$ 13,878</u>	<u>\$ 13,878</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:				
Warrant liability	\$ 882	\$ —	\$ —	\$ 882
Total liabilities	<u>\$ 882</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 882</u>

	Balance as of December 31, 2015	Fair value measurements at reporting date using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Money market funds(1)	\$ 3,593	\$ 3,593	\$ —	\$ —
U.S. Treasury bonds(2)	9,175	9,175	—	—
Total assets	<u>\$ 12,768</u>	<u>\$ 12,768</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:				
Warrant liability	\$ 332	\$ —	\$ —	\$ 332
Total liabilities	<u>\$ 332</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 332</u>

(1) Classified as cash and cash equivalents on the condensed consolidated balance sheets.

(2) Classified as short-term investments on the condensed consolidated balance sheets.

The Company's investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as of September 30, 2016 and December 31, 2015.

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

	September 30, 2016	December 31, 2015
Assumed risk-free interest rate	0.90% - 1.64%	1.28% - 2.06%
Assumed volatility	53.42% - 62.36%	66.76% - 70.66%
Expected life	2.40 - 8.00 yrs	3.15 - 8.75 yrs
Expected dividend yield	—%	—%
Preferred stock fair value:		
Series D	\$ 15.00	\$ 8.41
Series C-1	\$ 15.00	\$ 2.24
Series C	\$ 15.00	\$ 1.72

The assumptions were determined as follows:

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

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

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

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

Preferred stock fair value — On September 30, 2016, the Company was in the process of pricing its common stock for sale to the public and the midpoint of the pricing range was \$15.00. As all preferred stock would immediately convert to common stock upon the consummation of the IPO, the Company used \$15.00 as it represented the preferred stock fair value as of September 30, 2016. Given the absence of a public trading market on December 31, 2015, the Company considered numerous objective and subjective factors to determine the fair value of preferred stock at each valuation date. These factors included, but were not limited to, (i) contemporaneous valuations of preferred stock performed by unrelated third-party specialists; (ii) the prices for preferred stock sold to outside investors; (iii) the rights, preferences and privileges of preferred stock relative to common stock; (iv) developments in the business; and (v) the likelihood of achieving a liquidity event, such as an IPO or a merger or acquisition of the Company, given prevailing market conditions.

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

The following table provides reconciliation for all liabilities measured at fair value using significant unobservable inputs (Level 3) for the nine months ended September 30, 2016 and the year ended December 31, 2016 (in thousands):

	Fair value measurements at reporting date using significant unobservable inputs (Level 3)
Balance at December 31, 2014	\$ 56
Issuance of warrants for the purchase of convertible preferred stock	242
Change in fair value of warrant liability	34
Balance at December 31, 2015	332
Change in fair value of warrant liability	550
Balance at September 30, 2016	\$ 882

Instruments Not Recorded at Fair Value on a Recurring Basis

The estimated fair value of long-term debt is determined by Level 2 inputs and is based primarily on quoted market prices for the same or similar issues. The recorded value of long-term debt approximates the current fair value based the Second Amendment to the Loan and Security Agreement, or the 2016 Loan Agreement, entered into with Pacific Western Bank in September 2016.

4. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	\$ (5,260)	\$ (3,562)	\$ (12,972)	\$ (10,719)
Weighted-average common shares outstanding, basic and diluted	963,724	574,044	706,688	572,818
Net loss per share, basic and diluted	\$ (5.46)	\$ (6.21)	\$ (18.36)	\$ (18.71)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Convertible preferred stock, on an as-if-converted basis	10,360,419	8,443,994	9,524,692	8,443,994
Stock options to purchase common stock	163,967	—	220,818	—
Total	<u>10,524,386</u>	<u>8,443,994</u>	<u>9,745,510</u>	<u>8,443,994</u>

5. Balance Sheet Details

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

	Maturity (in years)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
At September 30, 2016:					
U.S. Treasury	1 year or less	\$ 11,828	\$ 1	\$ —	\$ 11,829
At December 31, 2015:					
U.S. Treasury	1 year or less	\$ 9,178	\$ —	\$ (3)	\$ 9,175

Inventory consist of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	\$ 315	\$ 235
Work in process	12	121
Finished goods	111	7
Total	<u>\$ 438</u>	<u>\$ 363</u>

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

	September 30, 2016	December 31, 2015
Deferred offering costs	\$ 2,363	\$ —
Prepaid assets	353	234
Interest receivable	52	25
Other assets	89	14
Total	<u>\$ 2,857</u>	<u>\$ 273</u>

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

	September 30, 2016	December 31, 2015
Computer equipment	\$ 295	\$ 255
Leasehold improvements	193	181
Furniture and fixtures	93	82
Scientific equipment	829	770
Construction in progress, or CIP	159	24
	1,569	1,312
Less: accumulated depreciation and amortization	(1,034)	(894)
Total	\$ 535	\$ 418

Depreciation and amortization expense was \$0.1 million for both the nine months ended September 30, 2016 and 2015.

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

	September 30, 2016	December 31, 2015
Accrued IPO costs	\$ 993	\$ —
Accrued professional fees	677	195
Accrued legal	257	162
Accrued interest	38	44
Other accrued expenses	469	92
Total	\$ 2,434	\$ 493

6. Term Loan

In June 2013, the Company entered into a loan and security agreement, or 2013 Loan Agreement, with Square 1 Bank allowing for borrowings up to \$3.0 million. In addition to the interest payments, Square 1 Bank received warrants for the purchase of up to 8,693 shares of the Company's Series C-1 convertible preferred stock. In October 2014, the Company amended the 2013 Loan Agreement and executed a \$10.0 million credit facility with Square 1 Bank, or 2014 Loan Agreement. The 2014 Loan Agreement was separated into two tranches, Term Loan A and Term Loan B. Term Loan A was \$5.0 million, which included the existing \$3.0 million of outstanding debt and the additional \$2.0 million that was funded upon closing of the 2014 Loan Agreement. Term Loan B was \$5.0 million and was available upon receipt of at least \$20.0 million in proceeds from the issuance and sale of the Company's equity securities to investors. Term Loan B was funded after the close of the Company's Series D financing in January 2015. As part of the 2014 Loan Agreement, the Company issued Square 1 Bank additional warrants to purchase up to 27,869 shares of its Series D convertible preferred stock at \$7.5351 per share.

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

On September 7, 2016, the Company entered into the 2016 Loan Agreement, with Pacific Western Bank (as successor in interest to Square 1 Bank), which amends the existing outstanding debt agreement described above. The 2016 Loan Agreement allows for total borrowings up to \$15.0 million in two tranches as follows: a first tranche consisting of \$10.0 million funded on September 7, 2016, of which the full \$10.0 million must be used to repay the existing debt with Pacific Western Bank on a net settlement basis (pursuant to its original terms); and a second tranche consisting of an additional \$5.0 million which may be drawn at any time prior to March 7, 2017. The first tranche and the second tranche are collectively referred to as the "Term Loans." The Term Loans bear interest at the greater of prime rate plus 1.50% per annum, or 5.00%. The Term Loans mature on September 7, 2020 and have an interest-only period through March 2018 followed by 30 equal monthly installments of principal and interest. The Term Loans may be prepaid in full at any time with no additional cost.

The present value of the future cash flows under the 2016 Loan Agreement did not exceed the present value of the future cash flows under the 2014 Loan Agreement terms by more than 10%. As such, the Company treated the 2016 Loan Agreement as a modification and recorded the associated immaterial facility fee as a discount to the 2016 Loan Agreement. This discount and the remaining balance of debt issuance costs and debt discount of the 2014 Loan Agreement are amortized to interest expense over the remaining term of the 2016 Loan Agreement using the effective-interest method.

Pursuant to the 2016 Loan Agreement, the Company issued to Pacific Western Bank a warrant to purchase a number of the Company's Series E Preferred Stock, at a purchase price of \$8.2932 per share, equal to 3.0% of the total amount of up to \$5.0 million of debt drawn over \$10.0 million divided by the purchase price, which automatically converted into a warrant to purchase the same number of shares of common stock immediately prior to the closing of the Company's IPO, and will only be exercisable in the event that the Company borrows all or part of the second tranche. As the Company has not drawn down on the second tranche, none of these warrants are exercisable as of September 30, 2016.

The 2016 Loan Agreement also requires that, if the Company's total cash is less than \$15.0 million, the Company is required to maintain all its deposits, transaction accounts and primary investment accounts with Pacific Western Bank, and if the Company's total cash is greater than \$15.0 million, it is required to maintain 50% of its deposits, transaction accounts and primary investment accounts with Pacific Western Bank. In addition, should the Company draw on the second tranche and its cash balance fall below \$5.0 million, the Company is required to deliver a signed term sheet to Pacific Western Bank that is reasonably acceptable to the bank for the sale of the Company's equity securities.

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

	September 30, 2016
Face value	\$ 10,000
Less: debt issuance costs	(114)
Total long-term loan	\$ 9,886
Less: current portion of long-term loan	—
Total long-term loan, excluding current portion	\$ 9,886

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

Year ended:	
December 31, 2016	\$ —
December 31, 2017	—
December 31, 2018	3,000
December 31, 2019	4,000
December 31, 2020	3,000
Total future principal payments due under the 2016 Loan Agreement	\$ 10,000

7. Stock-Based Compensation

The Company adopted an Equity Incentive Plan, or the Plan, in 2008, under which 2,380,074 shares of common stock are reserved for issuance to employees, nonemployee directors, and consultants of the Company. The Plan provides for the grant of incentive stock options, nonstatutory stock options, rights to purchase restricted stock, stock appreciation rights, dividend equivalents, stock payments, and restricted stock units to eligible recipients.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Assumed risk-free interest rate	1.42%	1.57%	1.42%-1.53%	1.57%
Assumed volatility	52.96%	61.53%	52.96%-53.49%	61.53%
Expected option life	6.1 years	6.1 years	6.1 years	6.1 years
Expected dividend yield	—%	—%	—%	—%

The Company recognized stock-based compensation straight-line over the vesting term of the options. The Company recorded non-cash compensation, including non-cash compensation to employees and nonemployees in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of revenue	\$ 8	\$ 8	\$ 23	\$ 23
Research and development	13	12	38	35
Selling, general and administrative	34	33	139	95
Total	<u>\$ 55</u>	<u>\$ 53</u>	<u>\$ 200</u>	<u>\$ 153</u>

Unrecognized compensation expense at September 30, 2016 was approximately \$0.8 million, which is expected to be recognized over a weighted-average term of 3.3 years.

Equity instruments issued to nonemployees are initially recorded at their grant-date fair value and are periodically revalued using the Black-Scholes Option Pricing model as the equity instruments vest and are recognized as expense over the related service period. Stock-based compensation expense to nonemployees was immaterial for the nine months ended September 30, 2016 and 2015.

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

	Number of shares	Weighted- average exercise price	Weighted- average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2015	1,298,868	\$ 1.44		
Options granted	740,782	1.85		
Options exercised	(808,498)	1.32		
Options canceled	(41,904)	2.23		
Outstanding at September 30, 2016	<u>1,189,248</u>	<u>\$ 1.74</u>	8.3	\$ 15,503
Vested and expected to vest at September 30, 2016	1,098,691	\$ 1.75	8.3	\$ 14,298
Vested and exercisable at September 30, 2016	397,373	\$ 1.76	6.5	\$ 4,998

All options outstanding are exercisable under the early exercise provisions of the Plan. Options granted under the Plan that are exercised prior to vesting are subject to repurchase by the Company at the original issue price and will vest according to the respective option agreement. For the nine months ended September 30, 2016, 252,453 options were early exercised and 246,927 remain unvested as of September 30, 2016 with a related liability of \$0.3 million recorded under other current liabilities on the Company's condensed consolidated balance sheet as of September 30, 2016.

8. Convertible Preferred Stock and Stockholders' Deficit

Convertible Preferred Stock

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

	As of September 30, 2016			
	Shares authorized	Shares issued and outstanding	Net carrying value	Aggregate liquidation preference
Series A	2,333,332	804,595	\$ 6,773	\$ 7,000
Series B	4,333,332	1,494,248	6,454	6,500
Series C	7,809,006	2,668,533	16,393	16,523
Series C-1	1,418,042	480,286	4,984	5,000
Series D	8,076,436	2,732,552	20,095	20,590
Series E	10,490,611	1,916,425	15,799	15,893
Total	34,460,759	10,096,639	\$ 70,498	\$ 71,506

Outstanding Warrants

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

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

Series E Preferred Stock

On April 29, 2016, the Company completed its Series E financing. The Company sold 1,916,425 shares of Series E stock at \$8.2932 per share for cash proceeds of \$15.8 million, gross of \$0.1 million in issuance costs. The holders of Series E stock are entitled to receive dividends, if declared, at a rate of \$0.6635 per annum. In the event of liquidation, the holders of Series E shares are entitled to receive liquidation preferences at the rate of \$8.2932 per share. Each share of Series E stock is convertible to one share of common stock immediately upon (i) the Company's sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, in which per share price is at least \$12.44 (as adjusted) or (ii) the affirmative vote of more than 67% of the holders of the then-outstanding preferred stock voting together as a single class.

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

Amendments to Certificate of Incorporation

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

- increase the total number of shares authorized from 63,805,954 to 79,460,759, of which 45,000,000 are designated as common stock and 34,460,759 are designated as preferred stock;
- reduce the liquidation preference on Series D preferred stock from \$15.0701 per share to \$7.5351 per share;
- create three classes of preferred stock- Series E, Series D and Junior preferred stock. Holders of Series E preferred stockholder receive payment of liquidation distributions and dividends prior and in preference to holders of Series D and Junior preferred stock. Holders of Series D preferred stock receive payment of liquidation distributions and dividends prior and in preference to holders of Junior preferred stock. Liquidation distributions to holders of Junior preferred stock are made pari passu and are made in preference to any payments to the holders of common stock;

- modify the IPO price at which each share of preferred stock is automatically converted to common from \$11.3025 per share to \$12.44 per share (as adjusted for Recapitalizations); and
- change the automatic conversion of the preferred stock to no longer require the affirmative vote of more than 67% of the Series D convertible preferred stock, but only requiring the affirmative vote of more than 67% of the holders of then outstanding preferred stock voting together as a single class.

On October 12, 2016, the Company's certificate of incorporation was further amended in connection with the closing of the IPO. See Note 12 for further detail.

Common Stock Reserved for Future Issuance

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

Conversion of preferred stock	10,360,419
Stock options issued and outstanding	1,189,248
Authorized for future option grants	223,371
Warrants outstanding	85,336
Total common stock	<u>11,858,374</u>

9. Income Taxes

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

10. Commitments and Contingencies

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

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

Year ended:	
December 31, 2016	\$ 71
December 31, 2017	<u>71</u>
Total future payments due under building lease	<u>\$ 142</u>

Rent expense was \$0.2 million for both nine months ended September 30, 2016 and 2015, respectively.

11. Related Party Transactions

In June 2013, the Company and Bader Sultan & Bros. Co W.L.L., or Bader, a healthcare products distributor based in Sufat, Kuwait, entered into a distribution agreement, whereby the Company appointed Bader as a distributor of its products. Sales to Bader began in November 2013. The Company's agreement with Bader restricts Bader's ability to sell competing products and requires Bader to purchase a certain number of products from the Company monthly based on annual forecasts that the Company provides to Bader. If Bader does not resell the minimum purchase quantity specified in the contract by the applicable date, then the Company has the right, in its sole discretion, to sell to other distributors in the Middle East or terminate its agreement with Bader. The initial term of the agreement expires in December 2019, and will thereafter automatically renew for successive terms of 12 months, subject to certain exceptions. The agreement can be terminated by the Company immediately upon certain breaches by Bader, or by either Bader or the Company for uncured material breach of the agreement.

As part of the 2014 Series D convertible preferred stock financing, Bader purchased 875,903 shares of the Company's Series D convertible preferred stock. All terms of the purchase of preferred stock were the same for Bader as the other investors. Sales to Bader for the nine months ended September 30, 2016 totaled \$2.6 million, which represent 100% of total revenue for the period. As of September 30, 2016, the Company had accounts receivable from Bader of \$0.5 million.

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

12. Subsequent Events

Initial Public Offering

In connection with the IPO discussed in Note 1, the following events occurred:

- An aggregate of 10,360,419 shares of common stock were issued to the holders of the Company's Series A, Series B, Series C, Series C-1, Series D and Series E convertible preferred stockholders upon the automatic conversion of all shares of convertible preferred stock to common stock immediately prior to the closing of the IPO.
- 12,217 shares of common stock were issued upon the automatic net exercise of warrants to purchase an aggregate of 24,550 shares of convertible preferred stock.
- Warrants exercisable for an aggregate of 60,786 shares of convertible preferred stock automatically converted into warrants exercisable for an aggregate of 60,786 shares of common stock.
- The 2016 Equity Incentive Plan, or 2016 Plan, and the 2016 Employee Stock Purchase Plan, or 2016 ESPP, as described below, were adopted.
- An aggregate of 223,371 shares of common stock reserved but not issued under the 2008 Plan became available for grant under the 2016 Plan.
- The Company filed its amended and restated certificate of incorporation on October 12, 2016, authorizing 300,000,000 shares of common stock and 10,000,000 shares of preferred stock.

Adoption of 2016 Equity Incentive Plan

On October 4, 2016, the 2016 Plan became effective. The 2016 Plan serves as a successor to the 2008 Plan. The 2016 Plan permits the award of stock options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards, cash awards and stock bonuses. The Company reserved 2,200,000 shares of common stock for issuance under the 2016 Plan, plus the 223,271 reserved and unissued shares under the 2008 plan on the effective date of the 2016 Plan. The number of shares reserved for issuance under the 2016 Plan will increase automatically on January 1 of each calendar year continuing through the tenth calendar year during the term of the 2016 Plan by the number of shares equal to 4% of the total outstanding shares of our common stock and common stock equivalents as of the immediately preceding December 31.

Adoption of 2016 Employee Stock Purchase Plan

On October 5, 2016, the 2016 ESPP became effective. The 2016 ESPP was adopted in order to enable eligible employees to purchase shares of the Company's common stock at a discount. Purchases will be accomplished through participation in discrete offering periods. The Company initially reserved 180,000 shares of common stock for issuance under the 2016 ESPP. The number of shares reserved for issuance under the 2016 ESPP will increase automatically on January 1 of each calendar year beginning after the first offering date and continuing through the first ten calendar years by the number of shares equal to 1% of the total outstanding shares of our common stock and common stock equivalents as of the immediately preceding December 31.

Warrant Exercises

On October 10, 2016, warrants for 36,562 shares of the Company's common stock were exercised by Pacific Western Bank via cashless exercise resulting in the issuance of 16,558 shares of common stock.

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

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

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

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2015, included in our prospectus dated October 5, 2016, filed with the Securities and Exchange Commission, or SEC, on October 6, 2016 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus.

OVERVIEW

We are a commercial-stage medical device company focused on developing and commercializing innovative medical devices to treat obese and overweight people. Our initial product offering is the Obalon balloon system, the first and only U.S. Food and Drug Administration, or FDA approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients. In September 2016, we received premarket approval from the FDA, to market our balloon system for temporary use to facilitate weight loss in obese adults with a body mass index, or BMI, of 30 to 40, who have failed to lose weight through diet and exercise. The Obalon balloon system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. The Obalon balloon system has the potential to provide patients and physicians with a cost-effective, reversible and repeatable weight loss solution in an outpatient setting, without altering patient anatomy or requiring surgery. We anticipate commencing the U.S. commercial launch of our Obalon balloon system in early 2017. As of September 30, 2016, we had sold over 25,000 of our earlier generation Obalon balloon systems for commercial use outside the United States.

We began selling an earlier version of our Obalon balloon system in international markets in the third quarter of 2012. In 2015, we discontinued sales in certain international markets to conserve financial resources. We continued distribution of our earlier generation product in the Middle East while we focused on developing our current Obalon balloon system for both the US and international markets. In 2017, we intend to discontinue international distribution of our earlier generation product and begin selling our current Obalon balloon system.

In June 2013, we entered into a distribution agreement with Bader Sultan & Bros. Co W.L.L., or Bader, a healthcare products distributor based in Sufat, Kuwait, which subsequently became one of our significant stockholders. Pursuant to the distribution agreement, in November 2013, we began selling our earlier generation Obalon balloon system to Bader, our sole distributor in the Middle East. Sales to Bader for the nine months ended September 30, 2016 and 2015 totaled \$2.6 million and \$2.8 million, which represented 100% and 92.7% of total revenue, respectively. As of September 30, 2016, all of our total revenue consisted of sales of our earlier generation Obalon balloon system to Bader. We expect Bader to account for a significantly lower percentage of our total revenue as we commence commercial sales in the United States in 2017.

We intend to focus our sales and marketing efforts primarily on selling our product in the United States through a direct sales force, as well as selling our products through Bader in the Middle East and other distributors in select international markets. We are building a direct sales organization consisting of regional sales directors, executive account managers and product specialists. We initially plan to sell the Obalon balloon system on a self-pay basis into existing physician specialty areas with weight loss practices, such as bariatric surgeons and gastroenterologists. In addition, we are targeting plastic surgeons, as we believe they have experience managing self-pay and cash pay practices. Given the initial focus of our sales and marketing efforts, we are targeting the U.S. market with a sales organization of approximately 20 to 25 individuals.

We generated total revenue, including revenue recognized from related parties, of \$0.8 million and \$1.1 million for the three months ended September 30, 2016 and 2015, respectively and \$2.6 million and \$3.1 million for the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016 and 2015, our net loss was \$13.0 million and \$10.7 million, respectively. We have not been profitable since inception, and as of September 30, 2016, our accumulated deficit was \$69.1 million. From inception through September 30, 2016, we financed our operations primarily through private placements of our preferred securities and, to a lesser extent, debt financing arrangements.

On October 5, 2016, our Registration Statement on Form S-1/A (File No. 333-213551) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 5,000,000 shares of our common stock at a price of \$15.00 per share for aggregate cash proceeds of approximately \$67.4 million, net of underwriting discounts, commissions, and estimated offering costs. The sale of 5,000,000 shares in the IPO closed on October 12, 2016.

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

COMPONENTS OF OUR RESULTS OF OPERATIONS

Revenue

Total revenue consists of international sales of an earlier generation of our Obalon balloon system. Revenue consists of sales of our Obalon balloon system to distributors or directly to physicians in international markets outside of the Middle East, and revenue, related party reflects sales of our Obalon balloon system to Bader in the Middle East. During the third quarter of 2015, we discontinued sales in international markets other than the Middle East, and for the nine months ended September 30, 2016, total revenue consisted of sales of our Obalon balloon system to Bader in the Middle East.

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

Cost of revenue and gross margin

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

We calculate gross margin as gross profit divided by total revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to increase over the long term as our production volume increases and as we allocate the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby reducing our per unit manufacturing costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter as we continue to introduce new products and adopt new manufacturing processes and technologies.

Research and development expenses

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

- employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;
- cost of outside consultants who assist with technology development, regulatory affairs, clinical affairs and quality assurance;
- cost of clinical trial activities performed by third party medical partners; and
- cost of facilities, depreciation on R&D equipment and supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products and enhance existing products and technologies. However, we expect R&D expenses as a percentage of total revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

Selling, general and administrative expenses

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

RESULTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
(in thousands)				
Consolidated statements of operations data:				
Revenue:				
Revenue	\$ —	\$ —	\$ —	\$ 224
Revenue, related party	773	1,093	2,621	2,832
Total revenue	773	1,093	2,621	3,056
Cost of revenue	644	644	1,938	1,849
Gross profit	129	449	683	1,207
Operating expenses:				
Research and development	2,169	3,201	7,267	9,169
Selling, general and administrative	2,412	618	5,387	2,297
Total operating expenses	4,581	3,819	12,654	11,466
Loss from operations	(4,452)	(3,370)	(11,971)	(10,259)
Interest expense, net	(135)	(142)	(425)	(405)
Loss from change in fair value of warrant liability	(669)	(42)	(550)	(31)
Other expense, net	(4)	(8)	(26)	(24)
Net loss	(5,260)	(3,562)	(12,972)	(10,719)
Other comprehensive income (loss)	1	(2)	5	8
Net loss and comprehensive loss	<u>\$ (5,259)</u>	<u>\$ (3,564)</u>	<u>\$ (12,967)</u>	<u>\$ (10,711)</u>

Comparison of three months ended September 30, 2016 and 2015

Total revenue. Total revenue decreased \$0.3 million to \$0.8 million during the three months ended September 30, 2016, compared to \$1.1 million during the three months ended September 30, 2015. This decrease was primarily attributable to a decrease in the volume of balloon units sold in the Middle East, which was partially offset by an increase in the price per unit sold.

Cost of revenue. Cost of revenue remained consistent at \$0.6 million during the three months ended September 30, 2016. This was primarily attributable to a decrease in volume sold, offset by expenses related to our FDA's premarket approval of our product, including employee related expenses and a write down of obsolete material associated with our earlier generation product.

Research and development expenses. R&D expenses decreased \$1.0 million to \$2.2 million during the three months ended September 30, 2016, compared to \$3.2 million during the three months ended September 30, 2015. This decrease was primarily attributable to a \$1.3 million decrease in clinical trial expenses due to the conclusion of our SMART trial. This decrease was partially offset by a \$0.3 million increase in employee-related expenses associated with additional headcount and bonus expenses relating to FDA's premarket approval of our product.

Selling, general and administrative expenses. SG&A expenses increased \$1.8 million to \$2.4 million during the three months ended September 30, 2016, compared to \$0.6 million during the three months ended September 30, 2015. This increase was primarily attributable to a \$0.7 million increase in legal fees associated with increased intellectual property development and protection, \$0.6 million increase in employee-related expenses from an increase in headcount, and a \$0.5 million increase in outside consultants expense associated with sales and marketing activities in preparation for commercialization in the United States.

Interest expense, net. Interest expense, net remained relatively consistent at \$0.1 million for the three months ended September 30, 2015 and 2016.

Comparison of nine months ended September 30, 2016 and 2015

Total revenue. Total revenue decreased \$0.5 million to \$2.6 million during the nine months ended September 30, 2016, compared to \$3.1 million during the nine months ended September 30, 2015. This decrease was primarily attributable to a decrease in the volume sold as we discontinued sales of our previous generation product in international markets outside the Middle East beginning in the third quarter of 2015 and reduced the volume sold in the Middle East in preparation for transition to our current generation product in 2017, which was partially offset by an increase in the price per unit sold.

Cost of revenue. Cost of revenue increased \$0.1 million to \$1.9 million during the nine months ended September 30, 2016, compared to \$1.8 million during the nine months ended September 30, 2015. This increase was primarily attributable to increased payroll costs and changes in the allocation of production cost between R&D expense and cost of revenue. Cost of revenue was also impacted by approximately \$0.1 million of expenses related to FDA's premarket approval of our product, including a bonus accrual relating to such approval, and a write down of obsolete material associated with our earlier generation product.

Research and development expenses. R&D expenses decreased \$1.9 million to \$7.3 million during the nine months ended September 30, 2016, compared to \$9.2 million during the nine months ended September 30, 2015. This decrease was primarily attributable to a \$2.8 million decrease in clinical trial expenses due to the conclusion of our SMART trial. This decrease was partially offset by a \$0.7 million increase in employee-related expenses associated with additional headcount and a \$0.2 million increase due to outside consultants expenses associated with projects to prepare us for FDA audits during the nine months ended September 30, 2016.

Selling, general and administrative expenses. SG&A expenses increased \$3.1 million to \$5.4 million during the nine months ended September 30, 2016, compared to \$2.3 million during the nine months ended September 30, 2015. This increase was primarily attributable to a \$1.7 million increase in legal fees associated with increased intellectual property development and protection, a \$0.7 million increase in employee-related expenses from an increase in headcount and a \$0.7 million increase in outside consultants expenses associated with sales and marketing activities in preparation for commercialization in the United States.

Interest expense, net. Interest expense, net remained consistent at \$0.4 million for the nine months ended September 30, 2016 and 2015.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2016, we had cash and cash equivalents and short-term investments of \$14.2 million and an accumulated deficit of \$69.1 million. Our primary sources of capital have been private placements of preferred stock and the incurrence of debt. To date, we have raised an aggregate of \$70.5 million in proceeds from convertible preferred stock financings. Additionally, in June 2013, we incurred \$3.0 million of debt under a loan and security agreement with Square 1 Bank, which was amended in October 2014 to increase the outstanding debt to \$5.0 million with an additional \$5.0 million funded in January 2015. In September 2016, the loan and security agreement was subsequently amended to provide for an additional \$5.0 million in funding, which we may borrow at any time prior to March 7, 2017. As of September 30, 2016, our aggregate outstanding indebtedness under the loan and security agreement was \$10.0 million.

On October 5, 2016, our Registration Statement on Form S-1/A (File No. 333-213551) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 5,000,000 shares of our common stock at a price of \$15.00 per share for aggregate cash proceeds of approximately \$67.4 million, net of underwriting discounts, commissions, and estimated offering costs. The sale of 5,000,000 shares in the IPO closed on October 6, 2016.

Due to the FDA's recent approval of our Obalon balloon system, we expect to incur substantial additional expenditures in the next 12 months to support the commercial launch of our product in the United States beginning in early 2017. We believe that the net proceeds from our IPO, together with our existing cash and cash equivalents and short-term investments and expected revenue, will be sufficient to meet our capital requirements and fund our operations through the next two years. We expect our costs and expenses to increase in the future as we prepare for and commence U.S. commercialization of our Obalon balloon system, including the development of a direct sales force and the expansion of our manufacturing facilities, and as we continue to make substantial expenditures on research and development, including for conducting clinical trials of our products in development. Additionally, we expect to incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the costs and expenses of establishing our U.S. sales and marketing infrastructure and our manufacturing operations;
- the degree of success we experience in commercializing our Obalon balloon system;
- the revenue generated by sales of our Obalon balloon system and other products that may be approved in the United States;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our products under development;
- the costs and timing of developing variations of our Obalon balloon system, and, if necessary, obtaining FDA approval of such variations;
- the emergence of competing or complementary technological developments;
- the extent to which our Obalon balloon system is adopted by the physician community;

- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

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

Loan and security agreement

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

As of September 30, 2016, we could borrow up to \$15.0 million in two tranches as follows: a first tranche consisting of \$10.0 million which was carried over from our previous agreement in September 2016, and a second tranche of \$5.0 million which may be drawn by us any time prior to May 7, 2017. As of September 30, 2016, we have not drawn down on this second tranche, and had \$10.0 million outstanding under this loan and security agreement, which has a variable annual interest rate equal to the greater of the prime rate plus 1.50% or 5.0%, and matures in September 2020.

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

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

The loan and security agreement provides for restrictions on, among other things, our ability to incur additional indebtedness, change the name or location of our business, change our business, merge with or acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with our affiliates, create liens, sell assets, pay any subordinated debt, and store certain inventory and equipment with third parties. In addition, if our total cash is less than \$15.0 million, we are required to maintain all our deposits, transaction accounts and primary investment accounts with Pacific Western Bank, and if our total cash is greater than \$15.0 million, we are required to maintain 50% of our deposits, transaction accounts and primary investment accounts with Pacific Western Bank.

CASH FLOWS

	Nine Months Ended September 30,	
	2016	2015
Net cash (used in) provided by:		
Operating activities	\$ (13,593)	\$ (7,175)
Investing activities	(3,006)	(3,121)
Financing activities	15,567	5,061
Exchange rate effect	—	3
Net decrease in cash and cash equivalents	<u>\$ (1,032)</u>	<u>\$ (5,232)</u>

Net cash used in operating activities

During the nine months ended September 30, 2016, net cash used in operating activities was \$13.6 million, consisting primarily of a net loss of \$13.0 million and an increase in net operating assets of \$1.7 million, primarily related to deferred offering costs incurred during the quarter ended September 30, 2016. These items were partially offset by non-cash charges of \$1.1 million, consisting primarily of changes in the fair value of warrant liability, share-based compensation expense, depreciation and non-cash interest expense related to amortization of investment premium and debt discount.

During the nine months ended September 30, 2015, net cash used in operating activities was \$7.2 million, consisting primarily of a net loss of \$10.7 million, partially offset by a decrease in net operating assets of \$3.0 million and non-cash charges of \$0.6 million. The decrease in net operating assets consisted primarily of an increase in accrued expenses for our SMART trial and a customer deposit received from Bader. The non-cash charges primarily consisted of share-based compensation expense, depreciation and non-cash interest expense related to amortization of investment premium and debt discount.

Net cash used in investing activities

During the nine months ended September 30, 2016, net cash used in investing activities was \$3.0 million, consisting primarily of purchases of short-term investments, partially offset by maturities of short-term investments.

During the nine months ended September 30, 2015, net cash used in investing activities was \$3.1 million, consisting primarily of purchases of short-term investments, partially offset by maturities of short-term investments.

Net cash provided by financing activities

During the nine months ended September 30, 2016, net cash provided by financing activities was \$15.6 million, consisting of net proceeds of \$14.5 million from the issuance of Series E convertible preferred stock and proceeds of \$1.1 million from sale of common stock.

During the nine months ended September 30, 2015, net cash provided by financing activities was \$5.1 million, consisting primarily of proceeds of \$5.0 million from borrowings under our loan and security agreement with Pacific Western Bank.

OFF-BALANCE SHEET ARRANGEMENTS

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States 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.

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 Prospectus, except for the determination of the fair value of our common stock, which was used in estimating the fair value of stock-based awards at grant date. Prior to our IPO, our stock was not publicly traded, therefore we estimated the fair value of our common stock as discussed in the Prospectus. Following our IPO, we established a policy, using the closing sale price per share of our common stock as quoted on the NASDAQ Global Market on the date of grant, for purposes of determining the exercise price per share of our share-based awards to purchase common stock.

RECENT ACCOUNTING PRONOUNCEMENTS

Except as described in Note 2 to the Unaudited Interim Condensed Consolidated Financial Statements under the heading “Recent Accounting Pronouncements,” there have been no new accounting pronouncements or changes to accounting pronouncements during the three and nine months ended September 30, 2016, as compared to the recent accounting pronouncements described in the Prospectus that are of significance or potential significance to us.

JOBS ACT ACCOUNTING ELECTION

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

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

INTEREST RATE RISK

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

In addition, we have outstanding debt under our loan and security agreement with Pacific Western Bank that bears interest. As of September 30, 2016, our aggregate outstanding indebtedness was \$10.0 million, which bears interest at the rate equal to the greater of the prime rate plus 1.50% or 5.0%. We do not believe an immediate 10% increase in interest rates would have a material effect on interest expense for the loan with Pacific Western Bank, and therefore we do not expect our operating results or cash flows to be materially affected to any degree by a sudden change in market interest rates.

CREDIT RISK

As of December 31, 2015 and September 30, 2016, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

EFFECTS OF INFLATION

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

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2016, our disclosure controls and procedures were effective at the reasonable assurance level. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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, 2016 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. We are currently not a party to any legal proceedings that we believe would have a material adverse effect on our business, financial condition or results of operations.

ITEM 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. In that event, the market price of our common stock would likely decline, and you could lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS

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

We have a limited operating history and have focused primarily on research and development, clinical trials, product engineering and building our manufacturing capabilities. We have also conducted a commercial launch of a previous generation of the Obalon balloon system in certain international markets, but our commercial sales experience in these international markets has been limited and our total revenue to date is approximately \$11.4 million. We have incurred significant losses in each period since our inception in 2008, with net losses of \$5.3 million and \$13.0 million for the three and nine months ended September 30, 2016, respectively and of \$3.6 million and \$10.7 million for the three and nine months ended September 30, 2015, respectively. As of September 30, 2016, we had an accumulated deficit of approximately \$69.1 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop, seek and obtain regulatory approval for our Obalon balloon system and sell our Obalon balloon system internationally.

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

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

We were incorporated in 2008, and to date our business activities have been focused primarily on the development and regulatory approval of our Obalon balloon system. All of our revenue to date is, and we expect for the foreseeable future will be, attributable to sales of our Obalon balloon system and its component parts. Our commercial sales experience to date has been limited to sales to distributors in a limited number of countries outside the United States. We recently obtained premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, to market the current generation of our balloon system in the United States, and we expect that sales in the United States will account for a majority of our revenue for the foreseeable future. Our limited operating experience and lack of commercialization experience in what we expect will be our primary market make it difficult to evaluate our current business and predict our future prospects. A number of factors that are outside our control may contribute to fluctuations in our financial results, including:

- patient and physician demand for our Obalon balloon system, including the rate at which physicians recommend our Obalon balloon system to their patients;
- positive or negative media coverage, or public, patient and/or physician perception, of our Obalon balloon system, the procedures or products of our competitors, or our industry;
- any safety or efficacy concerns that arise through patient experience with our Obalon balloon system;

- unanticipated delays in product development or product launches;
- our ability to maintain our current or obtain further regulatory clearances or approvals;
- delays in, or failure of, product and component deliveries by our third-party suppliers;
- introduction of new procedures or products for treating obese or overweight patients that compete with our product;
- adverse changes in the economy that reduce patient demand for elective procedures; and
- performance of our international distributors.

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

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

Physicians and patients may be slow to adopt and use intragastric balloons, and adverse events or other negative developments involving other companies' intragastric balloons or other obesity treatments may further slow physician and patient adoption. If any of these events were to occur, our business and prospects would be negatively affected.

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

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

Additionally, because the market for intragastric balloons is new and developing and contains a limited number of market participants, our products could be negatively impacted by unfavorable market reactions to these other devices. If the use of these or future intragastric balloons results in serious adverse device events, or SADEs, or such products are subject to malfunctions or misuse, patients and physicians may attribute such negative events to intragastric balloons generally, which may adversely affect market adoption of our Obalon balloon system. Additionally, if patients undergoing treatment with our Obalon balloon perceive the weight loss inadequate or adverse events too numerous or severe as compared with the retreatment rates of alternative balloons or procedures, it will be difficult to demonstrate the value of our Obalon balloon system to patients and physicians. As a result, demand for our Obalon balloon system may decline or may not increase at the pace or to the levels we expect.

If we are unable to convince physicians to adopt our Obalon balloon system and recommend it to their patients, we may be unable to sell our products, grow our business or achieve profitability.

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

- long-standing relationships with competitors and distributors that sell other products and their competitive response and negative selling efforts;
- lack of experience with our products and concerns that we are relatively new to the obesity market, or concerns that our competitors offer greater support or have larger amounts of resources than our company;
- perceived liability risk generally associated with the use of new products and procedures;
- lack or perceived lack of sufficient clinical evidence supporting clinical benefits;
- reluctance to change to or use new products;
- perceptions that our products are unproven or experimental; and
- time and skill commitment that may be required to gain familiarity with a new system.

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

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

In addition to educating physicians on the clinical benefits of our Obalon balloon system, we must also train physicians on its safe and appropriate use. In particular, our FDA approved labeling requires physicians to complete an Obalon training program before they can place the device and for us to provide clinical support as needed. If we are unable to provide an adequate training program, product misuse may occur that could lead to SADEs. Many physicians may be unfamiliar with such treatments or find it more complex than competitive products or alternative treatments. As such, there is a learning process involved for physicians to become proficient in the use of our products and it may take several procedures for a physician to be able to use our Obalon balloon system comfortably. In addition, it is also critical for physicians to be educated and trained on best practices in order to achieve optimal results, including patient selection and eligibility criteria as well as complementary methods of use such as diet or behavioral modification programs. Convincing physicians to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. This training process may also take longer than we expect. In the event that physicians are not properly trained in the use of our Obalon balloon system, they may misuse or ineffectively use our products for the treatment of patients. As a result, patients may experience adverse events or not be able to enjoy the benefits of our system or achieve the weight loss outcomes they expect, leading to dissatisfaction and market rejection of our products. In addition, misuse of our products in any stage of the treatment may result in, among other things, patient injury, adverse side effects, negative publicity or lawsuits against us. Any of these events could have an adverse effect on our business and reputation.

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

Patients may be unable to successfully swallow the capsule that contains the Obalon balloon, potentially creating an economic disincentive for physicians in adopting our technology. In our SMART trial, 7.6% of the combined treatment and control group patients failed to swallow a capsule with the microcatheter attached despite success swallowing a placebo that did not have a catheter attached. There were also instances where balloon deployment was negatively impacted due to a leak in the microcatheter, which was caused by the patient biting the catheter during placement. There may be other reasons for unsuccessful placements that we are not yet aware of. If the balloon is not successfully placed for any reason, the patient may attempt to seek a refund or monetary damages for the

treatment. Alternatively, physicians that have paid us for a balloon, but have not been paid by their patient because of a treatment failure, may seek a refund or monetary damages from us. Either scenario could cause a negative financial impact for us and could also create ill will with patients and physicians.

Patients may experience SADEs as the result of the misuse or malfunction of, or design flaws in, our products, which could expose us to expensive litigation, divert management's attention and harm our reputation and business.

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

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

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

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

We have very limited experience as a company in the sales and marketing of our products, and no experience with sales and marketing in the United States. The majority of our product sales to date have been through a single international distributor in the Middle East, with a lesser percentage sold through distributors or directly to physicians in Europe and Mexico. We recently obtained FDA approval to market our Obalon balloon system in the United States, and we plan to launch the product with a direct sales force that we are currently in the process of building. Identifying and recruiting qualified sales personnel and training them in the use of our Obalon balloon system to achieve the level of clinical competency expected by physicians, and compliance with applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense and attention. It can take several months before our sales representatives are fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenues. In particular, there is significant competition for qualified and experienced sales personnel. If we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenues.

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

- the inability of our sales and marketing personnel to perform their duties and conduct business in a manner that is compliant with our internal policies and procedures and FDA law and regulations;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to recommend any current and future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- efforts by our competitors to commercialize products at or about the time when our product would be coming to market.

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

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

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

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

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

- the success of any sales and marketing programs, including direct-to-consumer marketing efforts, that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians offer the Obalon balloon system to their patients;
- the extent to which the Obalon balloon system satisfies patient expectations;
- the cost, safety, comfort, tolerability, ease of use, and effectiveness of the Obalon balloon system as compared to other treatments; and
- general consumer confidence, which may be impacted by economic and political conditions.

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

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

All of our product sales to date have occurred internationally using an earlier generation of the Obalon balloon system. We expect to transition our international sales to the current generation of the Obalon balloon system in 2017. As a result, we have no experience in manufacturing our current Obalon balloon system in commercial quantities, and we will need to increase our manufacturing capabilities in order to satisfy expected demand for our Obalon balloon system. We may encounter production delays or shortfalls caused by many factors, including the following:

- the timing and process needed to assimilate the changes necessary to enable our production processes to accommodate anticipated demand;
- shortages that we may experience in any of the key components or sub-assemblies that we obtain from third-party suppliers;
- delays that we may experience in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;
- delays that we may experience in seeking FDA review and approval of PMA supplements required for certain changes in manufacturing facilities, methods or quality control procedures;
- our limited experience in complying with the FDA's Quality System Regulation, or the QSR, which sets forth good manufacturing practice requirements for medical devices and applies to the manufacture of the components of our Obalon balloon system; and
- our ability to attract and retain qualified employees, who are in short supply, in order to increase our manufacturing output.

If we are unable to keep up with demand for our Obalon balloon system, our revenue could be impaired, market acceptance for our product could be harmed and our customers might instead purchase our competitors' products. Our inability to successfully manufacture components of our Obalon balloon system in quantities sufficient to meet expected demand would materially harm our business.

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

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

In addition, our reliance on third-party suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

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

- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the QSR or other applicable laws or regulations enforced by the FDA and state regulatory authorities;
- inability to ensure the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

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

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

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

- the costs and expenses of establishing our U.S. sales and marketing infrastructure and our manufacturing operations;
- the degree of success we experience in commercializing our Obalon balloon system;
- the revenue generated by sales of our Obalon balloon system and any other products that may be approved in the United States;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our products under development;
- the costs and timing of developing enhancements of our Obalon balloon system and obtaining FDA clearance or approval of such enhancements;
- the emergence of competing or complementary technological developments;
- the extent to which our Obalon balloon system is adopted by the physician community and patients;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- costs of operating as a public company and compliance with existing and future regulations; and
- the extent and scope of our general and administrative expenses.

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

unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

A majority of our historical revenue and all of our current revenue is derived from a single distributor that is also one of our principal stockholders.

Bader Sultan & Bros. Co. W.L.L., or Bader, is currently the sole distributor of our Obalon balloon system in the Middle East. Revenue received from Bader's distribution of our Obalon balloon system in the Middle East represented 100% of our total revenue for the first nine months ended September 30, 2016 and a majority of our total revenue for the nine months ended September 30, 2015. Although we intend to commence sales in the United States through a directed sales force, we expect Bader will continue to be a significant source of our revenue for the near term. While we have a contract with Bader that provides for certain minimum purchase requirements over the term of the agreement, restricts Bader's ability to sell competing products and limits Bader's ability to terminate the agreement, Bader may still devote insufficient resources to our products, sell competitive products or terminate its relationship with us. We also have limited control over Bader's sales and marketing efforts for our product. If Bader fails to effectively market and sell our products in full compliance with applicable laws, or if we are unable to maintain our existing relationship with Bader, we may not be able to find a distributor with the scale and resources of Bader, maintain existing levels of international revenue or realize expected long-term international revenue growth. In addition, since the Obalon balloon system is our sole source of revenue, a delay or failure by Bader to successfully market our Obalon balloon system or the loss of Bader as a distributor could have a significant impact on our revenues and financial health.

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

Marketing our Obalon balloon system outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our product development and regulatory strategy, we plan to expand into other select international markets, but we do not currently intend to devote significant additional resources to market our Obalon balloon system internationally. Our decision to market our product primarily in the United States in the near-term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our product internationally.

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

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

In the United States, our product competes with a variety of pharmaceuticals, surgical procedures and devices for the treatment of obese and overweight people. There are several competitors in the pharmaceutical segment including those recently approved by the FDA, including Vivus, Inc., Arena Pharmaceuticals, Inc., Orexigen Therapeutics, Inc., and those with older brands or generics including Takeda Pharmaceutical Company Ltd, AstraZeneca plc, and Actavis plc. Large competitors in the surgical segment for weight loss and obesity include Ethicon Inc. (subsidiary of Johnson & Johnson), Medtronic plc (formerly Covidien Ltd.) and Apollo EndoSurgery, Inc., which acquired the Lap-Band from Allergan plc and currently sells that device worldwide. After approximately a decade, four new devices were approved by the FDA in 2015 and 2016. Enteromedics Inc. received FDA approval for the Maestro, which is intended to create weight loss by vagal nerve stimulation. ReShape Medical Inc. and Apollo EndoSurgery, Inc. received FDA approval for the ReShape Duo Balloon and the ORBERA Balloon, respectively, each a traditional intragastric balloon filled with saline. Aspire Bariatrics received FDA approval for the Aspire Assist, a device that allows a patient to aspirate food after a meal. Allurion Technologies, Inc. has also developed a swallowable, passable saline-filled intragastric balloon that has been approved for sale in Europe. Additionally, there are many more companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, which could compete with us in the future.

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

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

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

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

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

We currently manufacture and assemble our Obalon balloon system in our single manufacturing facility in Carlsbad, California. Our products consist of components sourced from a variety of contract manufacturers, with final assembly completed at our facility. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, terrorism, flooding and power outages. Any of these may render it difficult or impossible for us to manufacture products for an extended period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products, particularly as the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems would require FDA review and approval of a PMA supplement.

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

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

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Although we have entered into employment agreements with some of our executive officers and key employees, each of them may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. For example, we recently hired our Chief Financial Officer, Vice President of Sales, Vice President of Marketing and Vice President of Quality Assurance. We could experience disruptions as each of these individuals begins to integrate into the business and build his or her respective departments. Alternatively, our President and Chief Executive Officer, Andrew Rasdal, has been with us

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

To execute our growth plan, we must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales executives. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize medical devices.

Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Diego area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, either because we are a public company or otherwise, it may harm our ability to recruit and retain highly skilled employees. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

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

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

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

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

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

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to help facilitate the clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and to comply with applicable regulations and standards, commonly referred to as good clinical practices, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical

trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product properly and on time. While we will have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful to support product approval of a commercially viable product, or at all, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances or approvals that we need to commercialize our products and delay commercialization.

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

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

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

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. Claims may be made by patients, healthcare providers or others selling our products. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians in connection with the placement of our Obalon balloon into patients. If these physicians are not properly trained or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and raw materials. This risk exists even if a device or product is cleared or approved for commercial sale by the FDA or other foreign regulators and manufactured in facilities registered with and regulated by the FDA or an applicable foreign regulatory authority.

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

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

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

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

- product recall or withdrawal from the market;
- withdrawal of clinical trial participants; and
- substantial monetary awards to patients or other claimants.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory, product development tasks, clinical data, and customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses or hackers, power losses, and computer system or data network failures. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks.

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

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

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

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

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

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

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

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

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

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

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

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

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

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for the year ending December 31, 2017, provide a management report on our internal control over financial reporting. However, while we remain an emerging growth company we will not be required to include the attestation report issued by our independent registered public accounting firm.

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

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

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

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

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

At December 31, 2015, we had federal, state and foreign tax net operating loss carryforwards, or NOLs, of approximately \$31.5 million, \$13.9 million and \$1.3 million, respectively. Each of the federal and state NOLs will begin expiring in 2028, unless previously utilized. The foreign NOLs will begin expiring in 2023, unless previously utilized. We also had federal and California research and development tax credit carryforwards totaling \$1.3 million and \$1.1 million, respectively. The federal research and development tax credit carryforward will begin to expire in 2028 unless previously utilized. The California research tax credits do not expire.

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

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

RISKS RELATED TO REGULATORY APPROVAL

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

The successful commercialization of our Obalon balloon system is dependent on the successful development and commercialization of future devices such as the EzPz inflation system, our next generation inflation system that is expected to replace the EzFill inflation system to inflate the balloon with gas. Additionally, we are evaluating our vegetable-based HydroxyPropylMethylCellulose, or HPMC, capsule, which is expected to replace the current animal-based gelatin capsule. The primary information to support the EzPz inflation system and HPMC capsule is anticipated to be in vitro testing including but not limited to software validation, human factors assessment, and biocompatibility evaluation of the capsule. It is not anticipated that human clinical data will be required to support these regulatory submissions; however, it is possible that the FDA may require this information, which could delay potential approval. To support this potential request we are also evaluating these products in our current SMARTCAR study. While we expect to successfully complete the in vitro testing required to submit a PMA supplement for both the EzPz inflation system and the HPMC capsule, there can be no guarantee that these product enhancements will be completed or that we will receive regulatory approval for the sale and marketing of the EzPz inflation system or the HPMC capsule in the United States. A number of companies in the medical device field have suffered significant setbacks during evaluation due to lack of efficacy or unacceptable safety issues, notwithstanding promising preliminary results. Because we are depending on EzPz inflation system and HPMC capsule to achieve our revenue goals in future years, failure to receive FDA approval, in a timely manner or at all, will harm our financial results and ability to become profitable. Even if we obtain such regulatory approval, our ability to successfully market the Obalon balloon system may be limited. If we cannot sell our Obalon balloon system with EzPz inflation system and the HPMC capsule as planned, our financial results could be harmed.

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

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

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

Modifications to products that are approved through a PMA application generally need FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals would have a material adverse effect on our business, financial condition and prospects.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;

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

Further, the FDA and European regulatory authorities strictly regulate the indications for use and associated promotional safety and effectiveness claims, including comparative and superiority claims vis a vis competitors' products, that may be made about products, such as the Obalon balloon system. In particular, a medical device may not be promoted for uses or indications that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. For example, we will not be able to promote or make claims for the Obalon balloon system for the treatment of patients outside of the BMI ranges specifically approved by the FDA or other regulatory authorities. In the United States, we received FDA approval of the Obalon balloon system for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40) who have failed to lose weight through diet and exercise. The Obalon balloon system is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed. Our pivotal trial inclusion and exclusion criteria included patients with a BMI of 30 to 40; thus, our approved labeling is limited to the same BMI range. We also will not be able to make comparative or superiority claims for the Obalon balloon system versus other products without scientific data supporting or establishing those claims, including possibly data from head-to-head clinical trials if appropriate. Our CE mark label includes patients with a BMI of 27 or greater. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at 10 to 15 sites in the United States to evaluate the safety and efficacy of our Obalon balloon system in 200 subjects over a twelve-month period, consisting of six months of treatment with the Obalon balloon system followed by six months of observation after balloon removal. We will be required to update our product labeling in a PMA supplement as results, including any adverse event data, from the post-approval study become available.

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

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

Once a medical device is approved, a manufacturer must notify the FDA of any modifications to the device. Any modification to a device that has received FDA clearance or approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires premarket clearance or approval from the FDA pursuant to a new 510(k) clearance or approval of a PMA supplement. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, notice in an annual report or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. Any modification to a PMA approved device requires a PMA supplement, notification to the FDA in a PMA annual report,

or possibly a new PMA. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or obtain approval of PMA supplements or new PMAs for modifications to, or additional indications for, our Obalon balloon system in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. If we make additional modifications in the future that we believe do not or will not require additional clearances or approvals and the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our Obalon balloon system as modified, which could harm our operating results and require us to redesign our Obalon balloon system. In these circumstances, we may be subject to significant enforcement actions.

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

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

In addition, as a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at 10 to 15 sites in the United States to evaluate the safety and efficacy of our Obalon balloon system in 200 subjects over a twelve-month period, consisting of six months of treatment with the Obalon balloon system followed by six months of observation after balloon removal. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data, from the post-approval study become available. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

If we initiate a correction or removal for one of our devices, issue a safety alert, or undertake a field action or recall to reduce a risk to health posed by the device, we would be required to submit a publically available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall, which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases, or administrative or judicial enforcement actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

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

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

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

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;

- customer notifications or repair, replacement or refunds;
- refusing our requests for 510(k) clearance or PMA approvals or foreign regulatory approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

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

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

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

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

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

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA in 2014 and 2016, with four and zero inspectional observations, respectively, noted during those inspections. Although we believe our manufacturing facilities and those of our critical component suppliers are in compliance with the QSR requirements, we can provide no assurance that we will continue to remain in compliance with the QSR. If our manufacturing facilities or those of any of our component suppliers are found to be in violation of applicable laws and regulations, or we or our suppliers have significant noncompliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for clearance or approval of new products or modified products;
- withdrawing clearances or approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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

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

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

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

Healthcare providers, physicians and others will play a primary role in the recommendation and ordering of, and treatment using, our Obalon balloon system. Although intragastric balloon products similar to our Obalon balloon system are not currently reimbursed by United States federal healthcare programs (such as Medicare or Medicaid) or other third-party payors, any future reimbursement by third-party payors could expose our business to broadly applicable fraud and abuse and other healthcare laws and regulations that would regulate the business, including laws that would regulate financial arrangements and relationships through which we market, sell and distribute the Obalon balloon system. Additionally, as a device manufacturer, we are still subject to certain healthcare fraud and abuse regulation, including those laws that apply to self-pay products, and enforcement by the federal government and the states in which we conduct our business.

Applicable and potentially applicable United States federal and state healthcare laws and regulations include, but are not limited to, the following:

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

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

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

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

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

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

- **Privacy and Security Laws.** The Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and accompanying regulations, which we collectively refer to as HIPAA, require certain entities, referred to as "covered entities" (including most healthcare providers and health plans), to comply with established standards, including standards regarding the privacy and security of protected health information, or PHI. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their "Business Associates," as such term is defined by HIPAA, which, among other things, obligate the Business Associates to safeguard the covered entity's PHI against improper use and disclosure. In addition, a Business Associate may face significant statutory and contractual liability if the Business Associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. We believe that we generally do not conduct our business in a manner that would cause us to be a Business Associate under HIPAA, but we are nevertheless committed to maintaining the security and privacy of patients' health information. Although we believe the business is not currently subject to HIPAA, there is no guarantee that government enforcement agencies will agree. Violation of HIPAA could result in the imposition of civil or criminal penalties.

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

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

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

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

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

Our research and development and manufacturing operations involve the use of hazardous substances and a greenhouse gas, and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances as well as the control and reduction of greenhouse gas emissions. In addition, our research and development and manufacturing operations produce biological waste materials, such as human and animal tissue, and waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third party 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, 2016, we held 13 issued U.S. patents and had 17 pending U.S. patent applications, as well as 18 international patents issued in Europe, Mexico, Australia, Canada, Asia, China and Israel and 36 pending international patent applications in Australia, Canada, Europe, Asia, the Middle East and South America. Our issued patents expire between the years 2023 and 2032.

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

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

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect the Obalon balloon system or any other products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our Obalon balloon system before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

- we will develop additional proprietary technologies or products that are separately patentable; or
- that our commercial activities or products will not infringe upon the patents of others.

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

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

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

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

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

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

From time to time, third parties, including our competitors as well as other industry participants and/or non-practicing entities, may allege that the Obalon balloon system or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. For example, we recently received and may from time to time in the ordinary course of business continue to receive, letters from third parties advising us of third-party patents that may relate to our business. The letters do not explicitly seek any particular action or relief from us. Although these letters do not threaten legal action, these letters may be deemed to put us on notice that continued operation of our business might infringe the patent rights of such third parties. If we decide not to seek a license or do not otherwise obtain a license to such third-party patents, there can be no assurance that we will not become subject to infringement claims or will not be forced to initiate legal proceedings in order to dispose of such actual or potential infringement claims or to seek to invalidate the claims of such third-party patents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The United States has recently enacted and is currently implementing the America Invents Act of 2011, a wide-ranging patent reform legislation. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

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

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

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

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

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

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

Our management has considerable discretion in the application of the net proceeds that we received from our IPO, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our IPO in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from our IPO in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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

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

Certain holders of shares of our common stock are also entitled to rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also intend to register shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they can be sold freely in the public market upon issuance, subject to volume limitations applicable to affiliates and the 180-day lock-up period under the lock-up agreements described above.

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

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

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

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

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance

practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

As of September 30, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a majority of our outstanding capital stock. As a result, this group of stockholders will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We could be subject to securities class action litigation.

In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition, reputation and cash flows. These factors may materially and adversely affect the market price of our common stock.

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

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

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan, also known as a "poison pill";
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

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

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

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

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

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

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

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

Recent Sales of Unregistered Securities

From July 1, 2016 to September 30, 2016, we granted to our directors, employees, consultants and other service providers options to purchase 229,528 shares of common stock under our 2008 Stock Plan with a per share exercise price of \$2.82. In the same period, we issued and sold 801,413 shares of common stock upon exercise of stock options issued under the 2008 Stock Plan to our directors, officers, employees, consultants and other service providers for cash consideration at prices ranging from \$0.76 to \$2.61 for an aggregate purchase price of \$1.1 million. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Rule 701 promulgated under the Securities Act of 1933, as amended.

On September 7, 2016, we issued a warrant to purchase that number of shares of its Series E convertible preferred stock, at a purchase price of \$8.2932 per share, equal to 3.0% of the total additional amount of debt drawn (up to \$5.0 million) under our loan and security agreement with Pacific Western Bank divided by the purchase price, which will only be exercisable in the event we borrow such additional amount. Such warrant is exercisable for up to a maximum of 18,087 shares of Series E convertible preferred stock, and converted into a warrant exercisable for up to a maximum of 18,087 shares of our common stock upon the completion of our initial public offering on October 12, 2016. The purchaser represented to us that it was an accredited investor. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(2) of the Securities Act or Regulation D promulgated under the Securities Act.

Use of Proceeds

On October 5, 2016, our Registration Statement on Form S-1/A (File No. 333-213551) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to the IPO, we sold an aggregate of 5,000,000 shares of our common stock at a price of \$15.00 per share. UBS Securities LLC, Canaccord Genuity Inc. and Stifel, Nicolaus & Company, Incorporated acted as joint book-running managers of the offering and as representatives of the underwriters. BTIG LLC acted as co-manager for the offering. The offering did not terminate before all of the securities registered in the Registration Statement were sold. On October 12, 2016, we closed the sale of such shares, resulting in net proceeds to us of \$67.4 million, after deducting underwriting discounts and commissions of approximately \$5.2 million, and estimated offering costs of approximately \$2.4 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates.

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

ITEM 3. Defaults Upon Senior Securities

Not applicable.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

Exhibit Number	Description of Document	Form	File No.	Exhibit Filing Date	Filed/Furnished Herewith
3.2	Restated Certificate of Incorporation	S-1	333-213551	9/26/16	
3.4	Restated Bylaws	S-1	333-213551	9/26/16	
4.1	Third Warrant to Purchase Stock issued to Pacific Western Bank to purchase shares of Series E Preferred Stock, dated September 7, 2016.	S-1	333-213551	9/9/16	
10.1	Form of Indemnity Agreement by and between the Registrant and its directors and officers	S-1	333-213551	9/26/16	
10.2	2016 Equity Incentive Plan and form of award agreements thereunder	S-1	333-213551	9/26/16	
10.3	2016 Employee Stock Purchase Plan and form of enrollment agreement	S-1	333-213551	9/26/16	
10.5	Obalon Therapeutics, Inc. Bonus Plan	S-1	333-213551	9/26/16	
10.6	Form of CEO Retention Agreement				X
10.7	Form of Executive Retention Agreement (Non-CEO)				X
10.8*	Distribution Agreement dated June 26, 2013 between the Registrant and Bader Sultan & Bros. Co. W.L.L., as amended	S-1	333-213551	9/9/16	
10.9	Loan and Security Agreement dated June 14, 2013 between the Registrant and Pacific Western Bank (as successor in interest to Square 1 Bank), as amended	S-1	333-213551	9/9/16	
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1†	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

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

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

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 10, 2016

by: /s/ Andrew Rasdal
President and Chief Executive Officer

Date: November 10, 2016

by: /s/ William Plovanic
Chief Financial Officer

RETENTION AGREEMENT

This Retention Agreement (the "**Agreement**") is entered into by and between Andrew Rasdal (the "**Executive**") and Obalon Therapeutics, Inc., a Delaware corporation (the "**Company**"), on October 10, 2016, and is effective on the first date on which a registration statement covering the initial public offering of the common stock of the Company is declared effective by the United States Securities and Exchange Commission (the "**Effective Date**").

1. **Term of Agreement.**

Except to the extent renewed as set forth in this Section 1, this Agreement shall terminate the earlier of the third (3rd) anniversary of the Effective Date (the "**Expiration Date**") or the date the Executive's employment with the Company terminates for a reason other than a Qualifying Termination or CIC Qualifying Termination; *provided however*, if a definitive agreement relating to a Change in Control has been signed by the Company on or before Expiration Date, then this Agreement shall remain in effect through the earlier of:

- (a) The date the Executive's employment with the Company terminates for a reason other than a Qualifying Termination or CIC Qualifying Termination, or
- (b) The date the Company has met all of its obligations under this Agreement following a termination of the Executive's employment with the Company due to a Qualifying Termination or CIC Qualifying Termination.

This Agreement shall renew automatically and continue in effect for three (3) year periods measured from the initial Expiration Date, unless the Company provides Executive notice of non-renewal at least three (3) months prior to the date on which this Agreement would otherwise renew.

2. **Qualifying Termination.** If the Executive is subject to a Qualifying Termination, then, subject to Sections 4, 9, and 10 below, Executive will be entitled to the following benefits:

- (a) **Severance Benefits.** The Company shall pay the Executive twelve (12) months of his or her monthly base salary (at the rate in effect immediately prior to the actions that resulted in the Qualifying Termination). The Executive will receive his or her severance payment in a cash lump-sum in accordance with the Company's standard payroll procedures which will be made on the first business day occurring after the sixtieth (60th) day following the Separation, *provided that* the Release Conditions have been satisfied.
- (b) **Equity.** Each of Executive's then-outstanding and unvested Equity Awards (as defined below), including awards that would otherwise vest only upon satisfaction of performance criteria (measured at 100% of target), shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award effective immediately prior to the Separation.
- (c) **Continued Employee Benefits.** If Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("**COBRA**"), the Company shall pay the full amount of Executive's COBRA premiums on behalf of the Executive for the Executive's continued coverage under the Company's health, dental and vision plans, including coverage for the Executive's eligible dependents, for the twelve (12) month period following the Executive's Separation or, if earlier, until Executive is eligible to be covered under another substantially equivalent medical insurance plan by a subsequent employer. Notwithstanding the foregoing, if the Company, in its sole discretion, determines that it cannot provide the foregoing subsidy of COBRA coverage without potentially violating or causing the Company to incur additional expense as a result of noncompliance with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive

would be required to pay to continue the group health coverage in effect on the date of the Separation (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence on the later of (i) the first day of the month following the month in which Executive experiences a Separation and (ii) the effective date of the Company's determination of violation of applicable law, and shall end on the earlier of (x) the effective date on which Executive becomes covered by a health, dental or vision insurance plan of a subsequent employer, and (y) the last day of the period twelve (12) months after the Separation, *provided that*, any taxable payments under Section 2(b) will not be paid before the first business day occurring after the sixtieth (60th) day following the Separation and, once they commence, will include any unpaid amounts accrued from the date of Executive's Separation (to the extent not otherwise satisfied with continuation coverage). However, if the period comprising the sum of the sixty (60)-day period described in the preceding sentence and the ten (10)-day period described in Section 7(e)(3) below spans two calendar years, then the payments which constitute deferred compensation subject to Section 409A will not in any case be paid in the first calendar year. Executive shall have no right to an additional gross-up payment to account for the fact that such COBRA premium amounts are paid on an after-tax basis.

3. **CIC Qualifying Termination.** If the Executive is subject to a CIC Qualifying Termination, then, subject to Sections 4, 9, and 10 below, Executive will be entitled to the following benefits:

(a) **Severance and Bonus Payments.** The Company or its successor shall pay the Executive (i) twelve (12) months of his or her monthly base salary (at the rate in effect immediately prior to the actions that resulted in the Separation) and (ii) a pro rata portion (based on number of months worked in the Company's fiscal year of the Separation) of Executive's then-current target bonus opportunity. Such payment shall be paid in a cash lump sum payment in accordance with the Company's standard payroll procedures, which payment will be made on the first business day occurring after the sixtieth (60th) day following the Separation, *provided that* the Release Conditions have been satisfied.

(b) **Equity.**

- (i) **Post-IPO Equity Awards.** Each of Executive's then-outstanding Post-IPO Equity Awards, including awards that would otherwise vest only upon satisfaction of performance criteria, shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award. "**Post-IPO Equity Awards**" means all options to purchase shares of Company common stock that are granted on or after the Effective Date, as well as any and all other stock-based awards granted to the Executive, including but not limited to stock bonus awards, restricted stock, restricted stock units or stock appreciation rights that are granted on or after the Effective Date. Subject to Section 4, the accelerated vesting described above shall be effective as of the Separation.
- (ii) **Pre-IPO Equity Awards.** For clarity, except as explicitly provided in Section 2(b) above and 3(b)(iii) below, any options to purchase shares of Company common stock that were granted prior to the Effective Date, regardless of whether or not exercised prior to the Effective Date ("**Pre-IPO Equity Awards**" and, together with the Post-IPO Equity Awards, the "**Equity Awards**"), shall not be affected by or subject to this Agreement, and such Pre-IPO Equity Awards shall continue to be governed by the vesting and acceleration provisions contained in the grant agreements for the Pre-IPO Equity Awards and, if applicable, any separate letter agreement pertaining to vesting acceleration of Pre-IPO Equity Awards entered into between the Company and Executive (such agreements, collectively, the "**Pre-IPO Equity Award Agreements**").
- (iii) **Non-Assumption of Equity Awards.** Notwithstanding anything to the contrary, if the successor or acquiring corporation (if any) of the Company refuses to assume, convert, replace or substitute Executive's unvested Equity Awards, as

provided in Section 2.1.1 of the Plan, in connection with a Corporate Transaction (as defined in the Plan), then notwithstanding any other provision in this Agreement, the Plan or any Pre-IPO Equity Award Agreement to the contrary, each of Executive's then-outstanding and unvested Equity Awards that are not assumed, converted, replaced or substituted, including awards that would otherwise vest only upon satisfaction of performance criteria (measured at 100% of target), shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award effective immediately prior to the Corporate Transaction.

- (iv) Death or Disability. Notwithstanding anything to the contrary herein, in the event Executive has a Separation due to Executive's death or Disability and such Separation occurs (i) within twelve (12) months following a Change in Control or (ii) within three (3) months preceding a Change in Control (but as to part (ii), only if the Separation occurs after a Potential Change in Control), each of Executive's then-outstanding and unvested Equity Awards, including awards that would otherwise vest only upon satisfaction of performance criteria (measured at 100% of target), shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award effective immediately prior to the Separation.

(c) **Pay in Lieu of Continued Employee Benefits.** If Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), the Company or its successor shall pay the full amount of Executive's COBRA premiums on behalf of the Executive for the Executive's continued coverage under the Company's health, dental and vision plans, including coverage for the Executive's eligible dependents, for the twelve (12) month period following the Executive's Separation or, if earlier, until Executive is eligible to be covered under another substantially equivalent medical insurance plan by a subsequent employer. Notwithstanding the foregoing, if the Company, in its sole discretion, determines that it cannot provide the foregoing subsidy of COBRA coverage without potentially violating or causing the Company to incur additional expense as a result of noncompliance with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue the group health coverage in effect on the date of the Separation (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage, shall commence on the later of (i) the first day of the month following the month in which Executive experiences a Separation and (ii) the effective date of the Company's determination of violation of applicable law, and shall end on the earlier of (x) the effective date on which Executive becomes covered by a health, dental or vision insurance plan of a subsequent employer, and (y) the last day of the period twelve (12) months after the Separation, *provided that*, any taxable payments under Section 3(c) will not be paid before the first business day occurring after the sixtieth (60th) day following the Separation and, once they commence, will include any unpaid amounts accrued from the date of Executive's Separation (to the extent not otherwise satisfied with continuation coverage). However, if the period comprising the sum of the sixty (60)-day period described in the preceding sentence and the ten (10)-day period described in Section 7(e)(3) below spans two calendar years, then the payments which constitute deferred compensation subject to Section 409A will not in any case be paid in the first calendar year. Executive shall have no right to an additional gross-up payment to account for the fact that such COBRA premium amounts are paid on an after-tax basis.

4. **General Release.** Any other provision of this Agreement notwithstanding, the benefits under Section 2 and 3 shall not apply unless the Executive (i) has executed a general release (in substantially the form attached hereto as Exhibit A) of all known and unknown claims that he or she may then have against the Company or persons affiliated with the Company and such release has become effective and (ii) has agreed not to prosecute any legal action or other proceeding based upon any of such claims. The release must be in the form prescribed by the Company, without alterations (this document effecting the foregoing, the "**Release**"). The Company will deliver the form of Release to the Executive within thirty

(30) days after the Executive's Separation. The Executive must execute and return the Release within the time period specified in the form.

5. **Accrued Compensation and Benefits.** Notwithstanding anything to the contrary in Section 2 and 3 above, in connection with any termination of employment (whether or not a Qualifying Termination or CIC Qualifying Termination), the Company shall pay Executive's earned but unpaid base salary and other vested but unpaid cash entitlements for the period through and including the termination of employment, including unused earned vacation pay and unreimbursed documented business expenses incurred by Executive through and including the date of termination (collectively "**Accrued Compensation and Expenses**"), as required by law and the applicable Company plan or policy. In addition, Executive shall be entitled to any other vested benefits earned by Executive for the period through and including the termination date of Executive's employment under any other employee benefit plans and arrangements maintained by the Company, in accordance with the terms of such plans and arrangements, except as modified herein (collectively "**Accrued Benefits**"). Any Accrued Compensation and Expenses to which the Executive is entitled shall be paid to the Executive in cash as soon as administratively practicable after the termination and, in any event, no later than two and one-half (2-1/2) months after the end of the taxable year of the Executive in which the termination occurs or at such earlier time as may be required by Section 10 below or to such lesser extent as may be mandated by Section 9 below. Any Accrued Benefits to which the Executive is entitled shall be paid to the Executive as provided in the relevant plans and arrangements.

6. **Covenants.**

(a) **Non-Competition.** The Executive agrees that, during his or her employment with the Company, he or she shall not engage in any other employment, consulting or other business activity (whether full-time or part-time) that would create a conflict of interest with the Company.

(b) **Cooperation and Non-Disparagement.** The Executive agrees that, during the six (6) month period following his or her cessation of employment, he or she shall cooperate with the Company in every reasonable respect and shall use his or her best efforts to assist the Company with the transition of Executive's duties to his or her successor. The Executive further agrees that, during this six-month period, he or she shall not in any way or by any means disparage the Company, the members of the Company's Board of Directors or the Company's officers and employees. The Company agrees that, during this six-month period, none of the members of its Board of Directors or its executive officers will disparage Executive.

7. **Definitions.**

(a) **"Cause"** means: (i) Executive's conviction for, or guilty plea to, a felony involving moral turpitude; (ii) a willful refusal by Executive to comply with the lawful and reasonable instructions of the Company, or to otherwise perform Executive's duties as lawfully and reasonably determined by the Company, in each case that is not cured by Executive (if such refusal is of a type that is capable of being cured) within 15 days of written notice being given to Executive of such refusal; (iii) any willful act or acts of dishonesty undertaken by Executive and intended to result in Executive's (or any other person's) material gain or personal enrichment at the expense of the Company or any of its customers, partners, affiliates, or employees; or (iv) any willful act of gross misconduct by Executive which is injurious to the Company.

(b) **"Code"** means the Internal Revenue Code of 1986, as amended.

(c) **"Change in Control"** For all purposes under this Agreement, a Change in Control shall mean a "Corporate Transaction," as such term is defined in the Plan, *provided that* the transaction (including any series of transactions) also qualifies as a change in control event under U.S. Treasury Regulation 1.409A-3(i)(5).

(d) **"CIC Qualifying Termination"** means a Separation (i) within twelve (12) months following a Change in Control or (ii) within three (3) months preceding a Change in Control (but as to part (ii), only if the Separation occurs after a Potential Change in Control) resulting, in either case (i) or (ii), from (A) the Company or its successor terminating the Executive's employment for any reason other than Cause or (B) the Executive voluntarily resigning his or her employment for Good Reason. A termination or resignation due to the Executive's death or disability shall not constitute a CIC Qualifying Termination; provided, however, that, solely for purposes of Section 3(b)(iv) hereof, Executive's Separation due to Executive's death or Disability shall constitute a CIC Qualifying Termination. A **"Potential Change in Control"** means the date of execution of a legally binding and definitive agreement for a corporate transaction which, if consummated, would constitute the applicable Change in Control (which for the avoidance of doubt, would include a merger agreement, but not a term sheet for a merger agreement). In the case of a termination following a Potential Change in Control and before a Change in Control, solely for purposes of benefits under this Agreement, the date of Separation will be deemed the date the Change in Control is consummated.

(e) **"Disability"** means the total and permanent disability of Executive as defined by, or determined under, the Company's (or, if applicable, the Company's successor or acquiring corporation's (if any)) long-term disability benefit plan as in effect at the time of Separation.

(f) **"Good Reason"** means, without the Executive's consent, (i) a reduction in Executive's then-current base salary (except for a reduction that is part of a proportional reduction of the base salaries of all Company executives), bonus opportunity or commissions opportunity; (ii) the offices of the Company that Executive is required to report to being moved such that Executive's usual commuting distance is increased by more than ten (10) miles; (iii) a material and adverse change to Executive's duties or responsibilities (iv) a change to Executive's title and/or role, after which Executive is not both the Chief Executive Officer of the top-level acquiring entity whose stock is publicly traded and a voting member of its Board of Directors; (v) Executive is not, so long as Executive is Chief Executive Officer of the Company, a voting member of the Company's Board of Directors; or (vi) the Company provides notice that this Agreement will not be renewed, as set forth in Section 1 hereof; provided, however, that a resignation by Executive shall not be considered to be for a "Good Reason" unless (i) Executive provides written notice to the Company's Board of Directors of the occurrence of the event which Executive contends constitutes Good Reason within ninety (90) days of the date such event occurs, which notice states Executive's intention to resign for a "Good Reason" under this Agreement as a result thereof, (ii) the Company does not effect a cure with respect to such event within thirty (30) days of receipt of such written notice, and (iii) Executive thereafter resigns and ceases to perform services as an employee of the Company within ten (10) days of the expiration of the Company's cure period.

(g) **"Plan"** means the Company's 2016 Equity Incentive Plan, as may be amended from time to time.

(h) **"Release Conditions"** mean the following conditions: (i) Company has received the Executive's executed Release in the form attached hereto as Exhibit A and (ii) any rescission period applicable to the Executive's executed Release has expired.

(i) **"Qualifying Termination"** means a Separation that is not a CIC Qualifying Termination, but which results from (i) the Company terminating the Executive's employment for any reason other than Cause or (ii) the Executive voluntarily resigning his or her employment for Good Reason. A termination or resignation due to the Executive's death or disability shall not constitute a Qualifying Termination.

(j) **"Separation"** means a "separation from service," as defined in the regulations under Section 409A of the Code.

8. **Successors.**

(a) **Company's Successors.** The Company shall require any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or

substantially all of the Company's business and/or assets, by an agreement in substance and form satisfactory to the Executive, to assume this Agreement and to agree expressly to perform this Agreement in the same manner and to the same extent as the Company would be required to perform it in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets or which becomes bound by this Agreement by operation of law.

(b) **Executive's Successors.** This Agreement and all rights of the Executive hereunder shall inure to the benefit of, and be enforceable by, the Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

9. **Golden Parachute Taxes.**

(a) **Best After-Tax Result.** In the event that any payment or benefit received or to be received by Executive pursuant to this Agreement or otherwise ("**Payments**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this subsection (a), be subject to the excise tax imposed by Section 4999 of the Code, any successor provisions, or any comparable federal, state, local or foreign excise tax ("**Excise Tax**"), then, subject to the provisions of Section 10, such Payments shall be either (A) provided in full pursuant to the terms of this Agreement or any other applicable agreement, or (B) provided as to such lesser extent which would result in no portion of such Payments being subject to the Excise Tax ("**Reduced Amount**"), whichever of the foregoing amounts, taking into account the applicable federal, state, local and foreign income, employment and other taxes and the Excise Tax (including, without limitation, any interest or penalties on such taxes), results in the receipt by Executive, on an after-tax basis, of the greatest amount of payments and benefits provided for hereunder or otherwise, notwithstanding that all or some portion of such Payments may be subject to the Excise Tax. Unless the Company and Executive otherwise agree in writing, any determination required under this Section shall be made by independent tax counsel designated by the Company and reasonably acceptable to Executive ("**Independent Tax Counsel**"), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required under this Section, Independent Tax Counsel may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code; *provided that* Independent Tax Counsel shall assume that Executive pays all taxes at the highest marginal rate. The Company and Executive shall furnish to Independent Tax Counsel such information and documents as Independent Tax Counsel may reasonably request in order to make a determination under this Section. The Company shall bear all costs that Independent Tax Counsel may reasonably incur in connection with any calculations contemplated by this Section. In the event that Section 9(a)(ii)(B) above applies, then based on the information provided to Executive and the Company by Independent Tax Counsel, Executive may, in Executive's sole discretion and within thirty (30) days of the date on which Executive is provided with the information prepared by Independent Tax Counsel, determine which and how much of the Payments (including the accelerated vesting of equity compensation awards) to be otherwise received by Executive shall be eliminated or reduced (as long as after such determination the value (as calculated by Independent Tax Counsel in accordance with the provisions of Sections 280G and 4999 of the Code) of the amounts payable or distributable to Executive equals the Reduced Amount). If the Internal Revenue Service (the "**IRS**") determines that any Payment is subject to the Excise Tax, then Section 9(b) hereof shall apply, and the enforcement of Section 9(b) shall be the exclusive remedy to the Company.

(b) **Adjustments.** If, notwithstanding any reduction described in Section 9(a) hereof (or in the absence of any such reduction), the IRS determines that Executive is liable for the Excise Tax as a result of the receipt of one or more Payments, then Executive shall be obligated to surrender or pay back to the Company, within one-hundred twenty (120) days after a final IRS determination, an amount of such payments or benefits equal to the "**Repayment Amount**." The Repayment Amount with respect to such Payments shall be the smallest such amount, if any, as shall be required to be surrendered or paid to the Company so that Executive's net proceeds with respect to such Payments (after taking into account the payment of the Excise Tax imposed on such Payments) shall be maximized. Notwithstanding the foregoing, the Repayment Amount with respect to such Payments shall be zero (0) if a Repayment

Amount of more than zero (0) would not eliminate the Excise Tax imposed on such Payments or if a Repayment Amount of more than zero would not maximize the net amount received by Executive from the Payments. If the Excise Tax is not eliminated pursuant to this Section 9(b), Executive shall pay the Excise Tax.

10. **Miscellaneous Provisions.**

(a) **Section 409A.** To the extent (i) any payments to which Executive becomes entitled under this Agreement, or any agreement or plan referenced herein, in connection with Executive's termination of employment with the Company constitute deferred compensation subject to Section 409A of the Code and (ii) Executive is deemed at the time of such termination of employment to be a "specified" employee under Section 409A of the Code, then such payment or payments shall not be made or commence until the earlier of (i) the expiration of the six (6)-month period measured from the Executive's Separation; or (ii) the date of Executive's death following such Separation; *provided, however*, that such deferral shall only be effected to the extent required to avoid adverse tax treatment to Executive, including (without limitation) the additional twenty percent (20%) tax for which Executive would otherwise be liable under Section 409A(a)(1)(B) of the Code in the absence of such deferral. Upon the expiration of the applicable deferral period, any payments which would have otherwise been made during that period (whether in a single sum or in installments) in the absence of this paragraph shall be paid to Executive or Executive's beneficiary in one lump sum (without interest). Except as otherwise expressly provided herein, to the extent any expense reimbursement or the provision of any in-kind benefit under this Agreement (or otherwise referenced herein) is determined to be subject to (and not exempt from) Section 409A of the Code, the amount of any such expenses eligible for reimbursement, or the provision of any in-kind benefit, in one calendar year shall not affect the expenses eligible for reimbursement or in kind benefits to be provided in any other calendar year, in no event shall any expenses be reimbursed after the last day of the calendar year following the calendar year in which Executive incurred such expenses, and in no event shall any right to reimbursement or the provision of any in-kind benefit be subject to liquidation or exchange for another benefit. To the extent that any provision of this Agreement is ambiguous as to its exemption or compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder are exempt from Section 409A to the maximum permissible extent, and for any payments where such construction is not tenable, that those payments comply with Section 409A to the maximum permissible extent. To the extent any payment under this Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. Payments pursuant to this Agreement (or referenced in this Agreement) are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the regulations under Section 409A.

(b) **Other Arrangements.** This Agreement supersedes any and all cash severance arrangements and vesting acceleration arrangements on change in control under any agreement governing Equity Awards, severance and salary continuation arrangements, programs and plans which were previously offered, or may be offered on the Effective Date or thereafter, by the Company to the Executive, including change in control severance arrangements and vesting acceleration arrangements pursuant to an agreement governing Equity Awards, employment agreement or offer letter, and Executive hereby waives Executive's rights to such other benefits, provided that this Agreement shall not supersede the acceleration of vesting arrangements of any Pre-IPO Equity Awards (except as explicitly provided in Sections 2(b) and 3(b)(iii) hereof). In no event shall any individual receive cash severance benefits under both this Agreement and any other vesting acceleration arrangement, severance pay or salary continuation program, plan or other arrangement with the Company, provided that this Agreement shall not supersede the acceleration of vesting arrangements of any Pre-IPO Equity Awards (except as explicitly provided in Section 3(b)(iii) hereof). For the avoidance of doubt, in no event shall Executive receive (i) payment under both Section 2 and Section 3 and/or (ii) acceleration of Equity Award vesting under (a) both Section 2 and Section 3 or (b) any combination of (x) Section 3(b)(iii), (y) Section 3(b)(i) and/or Section 3(b)(ii) and/or (z) Section 3(b)(iv), as applicable, in each case with respect to Executive's Separation.

(c) **Dispute Resolution.** To ensure rapid and economical resolution of any and all disputes that might arise in connection with this Agreement, Executive and the Company agree that any and all disputes, claims, and causes of action, in law or equity, arising from or relating to this Agreement or its enforcement, performance, breach, or interpretation, will be resolved solely and exclusively by final, binding, and confidential arbitration, by a single arbitrator, in San Diego County, and conducted by Judicial Arbitration & Mediation Services, Inc. ("**JAMS**") under its then-existing employment rules and procedures. Nothing in this section, however, is intended to prevent either party from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Each party to an arbitration or litigation hereunder shall be responsible for the payment of its own attorneys' fees.

(d) **Notice.** Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid or deposited with Federal Express Corporation, with shipping charges prepaid. In the case of the Executive, mailed notices shall be addressed to him or her at the home address which he or she most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(e) **Waiver.** No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than the Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(f) **Withholding Taxes.** All payments made under this Agreement shall be subject to reduction to reflect taxes or other charges required to be withheld by law.

(g) **Severability.** The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(h) **No Retention Rights.** Nothing in this Agreement shall confer upon the Executive any right to continue in service for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Company or any subsidiary of the Company or of the Executive, which rights are hereby expressly reserved by each, to terminate his or her service at any time and for any reason, with or without Cause.

(i) **Choice of Law.** The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California (other than its choice-of-law provisions).

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

EXECUTIVE

OBALON THERAPEUTICS, INC.

Andrew Rasdal

By:
Title:

EXHIBIT A

GENERAL RELEASE OF ALL CLAIMS AND COVENANT NOT TO SUE

This General Release of All Claims and Covenant Not to Sue (the "Release") is entered into between Andrew Rasdal ("Executive") and Obalon Therapeutics, Inc. (the "Company") (collectively, "the parties").

WHEREAS, on _____, Executive and the Company entered into a Retention Agreement with the Company (the "Retention Agreement," to which this Release is attached as Exhibit A);

WHEREAS, on _____, Executive's employment with the Company terminated (the "Separation Date");

WHEREAS, this agreement serves as the Release, pursuant to the Retention Agreement; and

WHEREAS, Executive and the Company desire to mutually, amicably and finally resolve and compromise all issues and claims surrounding Executive's employment and separation from employment with the Company;

NOW THEREFORE, in consideration for the mutual promises and undertakings of the parties as set forth below, Executive and the Company hereby enter into this Release.

1. **Acknowledgment of Payment of Wages:** By his signature below, Executive acknowledges that, on the Separation Date, the Company paid him for all wages, salary, bonuses, commissions, reimbursable expenses, accrued but unused vacation and any similar payments due him from the Company as of the Separation Date. By signing below, Executive acknowledges that the Company does not owe him any other amounts, except as may become payable under the Retention Agreement and the Release.

2. **Return of Company Property:** Executive hereby warrants to the Company that he has returned to the Company all property or data of the Company of any type whatsoever that has been in his possession, custody or control.

3. **Consideration:** In exchange for Executive's agreement to this Release and his other promises in the Retention Agreement and herein, and pursuant to the Retention Agreement, the Company agrees to provide Executive with the consideration set forth in Section _____ of the Retention Agreement. By signing below, Executive acknowledges that he is receiving the consideration in exchange for waiving his rights to claims referred to in this Release.

4. **General Release and Waiver of Claims:**

a. The payments and promises set forth in this Release are in full satisfaction of all accrued salary, vacation pay, bonus and commission pay, profit-sharing, stock, stock options, restricted stock units or other ownership interest in the Company, termination benefits or other compensation to which Executive may be entitled by virtue of his employment with the Company or his separation from the Company, including pursuant to the Retention Agreement. To the fullest extent permitted by law, Executive hereby releases and waives any other claims he may have against the Company and its owners, agents, officers, shareholders, employees, directors, attorneys, subscribers, subsidiaries, affiliates, successors and assigns (collectively "Releasees"), whether known or not known, including, without limitation, claims under any employment laws, including, but not limited to, claims of unlawful discharge, breach of contract, breach of the covenant of good faith and fair dealing, fraud, violation of public policy, defamation, physical injury, emotional distress, claims for additional compensation or benefits arising out of his employment or separation of employment, including pursuant to the Offer Letter, claims under Title VII of the 1964 Civil Rights Act, as amended, the California Fair Employment

and Housing Act and any other laws and/or regulations relating to employment or employment discrimination, including, without limitation, claims based on age or under the Age Discrimination in Employment Act or Older Workers Benefit Protection Act, and/or claims based on disability or under the Americans with Disabilities Act.

b. By signing below, Executive expressly waives any benefits of Section 1542 of the Civil Code of the State of California, which provides as follows:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR."

c. Executive and the Company do not intend to release claims that he may not release as a matter of law, including but not limited to claims for indemnity under California Labor Code Section 2802, or any claims for enforcement of this Release. To the fullest extent permitted by law, any dispute regarding the scope of this general release shall be determined by an arbitrator under the procedures set forth in the Dispute Resolution section set forth in the Retention Agreement.

5. Covenant Not to Sue:

a. To the fullest extent permitted by law, at no time subsequent to the execution of this Release will Executive pursue, or cause or knowingly permit the prosecution, in any state, federal or foreign court, or before any local, state, federal or foreign administrative agency, or any other tribunal, of any charge, claim or action of any kind, nature and character whatsoever, known or unknown, which he may now have, have ever had, or may in the future have against Releasees, which is based in whole or in part on any matter released by this Release.

b. Nothing in this paragraph shall prohibit Executive from filing a charge or complaint with a government agency where, as a matter of law, the parties may not restrict his right to file such administrative complaints. However, Executive understands and agrees that, by entering into this Release, he is releasing any and all individual claims for relief, and that any and all subsequent disputes between Executive and the Company shall be resolved through arbitration as provided in the Retention Agreement.

c. Nothing in this paragraph shall prohibit or impair Executive or the Company from complying with all applicable laws, nor shall this Release be construed to obligate either party to commit (or aid or abet in the commission of) any unlawful act.

6. Review of Release: Executive understands that he may take up to twenty-one (21) days to consider this Release and, by signing below, affirms that he was advised to consult with an attorney prior to signing this Release. Executive also understands that he may revoke this Release within seven (7) days of signing this document and that the consideration to be provided to him pursuant to Paragraph 2(c) of the Retention Agreement will be provided only at the end of that seven (7) day revocation period.

7. Effective Date: This Release is effective on the eighth (8th) day after Executive signs it, provided he has not revoked it as of that time.

[Remainder of page intentionally left blank.]

8. Other Terms of Retention Agreement Incorporated Herein: All other terms of the Retention Agreement to the extent not inconsistent with the terms of this Release are hereby incorporated in this Release as though fully stated herein and apply with equal force to this Release, including, without limitation, the provisions on Non-Competition, Cooperation and Non-Disparagement, Section 409A, Dispute Resolution and Choice of Law.

Dated: _____

Name:

Title:

For the Company

Dated: _____

Name: Andrew Rasdal

RETENTION AGREEMENT

This Retention Agreement (the "**Agreement**") is entered into by and between [Name] (the "**Executive**") and Obalon Therapeutics, Inc., a Delaware corporation (the "**Company**"), on _____, 2016, and is effective on the first date on which a registration statement covering the initial public offering of the common stock of the Company is declared effective by the United States Securities and Exchange Commission (the "**Effective Date**").

1. **Term of Agreement.**

Except to the extent renewed as set forth in this Section 1, this Agreement shall terminate the earlier of the third (3rd) anniversary of the Effective Date (the "**Expiration Date**") or the date the Executive's employment with the Company terminates for a reason other than a Qualifying Termination or CIC Qualifying Termination; *provided however*, if a definitive agreement relating to a Change in Control has been signed by the Company on or before Expiration Date, then this Agreement shall remain in effect through the earlier of:

- (a) The date the Executive's employment with the Company terminates for a reason other than a Qualifying Termination or CIC Qualifying Termination, or
- (b) The date the Company has met all of its obligations under this Agreement following a termination of the Executive's employment with the Company due to a Qualifying Termination or CIC Qualifying Termination.

This Agreement shall renew automatically and continue in effect for three (3) year periods measured from the initial Expiration Date, unless the Company provides Executive notice of non-renewal at least three (3) months prior to the date on which this Agreement would otherwise renew. For the avoidance of doubt, and notwithstanding anything to the contrary in Section 2 or 3 below, the Company's non-renewal of this Agreement shall not constitute a Qualifying Termination or CIC Qualifying Termination, as applicable.

2. **Qualifying Termination.** If the Executive is subject to a Qualifying Termination, then, subject to Sections 4, 9, and 10 below, Executive will be entitled to the following benefits:

- (a) **Severance Benefits.** The Company shall pay the Executive [twelve (12)]¹ / [six (6)]² months of his or her monthly base salary (at the rate in effect immediately prior to the actions that resulted in the Qualifying Termination). The Executive will receive his or her severance payment in a cash lump-sum in accordance with the Company's standard payroll procedures which will be made on the first business day occurring after the sixtieth (60th) day following the Separation, *provided that* the Release Conditions have been satisfied.
- (b) **Continued Employee Benefits.** If Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("**COBRA**"), the Company shall pay the full amount of Executive's COBRA premiums on behalf of the Executive for the Executive's continued coverage under the Company's health, dental and vision plans, including coverage for the Executive's eligible dependents, for the [twelve (12)]³ / [six (6)]⁴ month period following the Executive's Separation or, if earlier, until Executive is eligible to be covered under another substantially equivalent medical insurance plan by a subsequent employer. Notwithstanding the foregoing, if the Company, in its sole discretion,

¹ CFO

² Executive officers who are not CEO or CFO

³ CFO

⁴ Executive officers who are not CEO or CFO

determines that it cannot provide the foregoing subsidy of COBRA coverage without potentially violating or causing the Company to incur additional expense as a result of noncompliance with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue the group health coverage in effect on the date of the Separation (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence on the later of (i) the first day of the month following the month in which Executive experiences a Separation and (ii) the effective date of the Company's determination of violation of applicable law, and shall end on the earlier of (x) the effective date on which Executive becomes covered by a health, dental or vision insurance plan of a subsequent employer, and (y) the last day of the period twelve (12)⁵ / [six (6)]⁶ months after the Separation, *provided that*, any taxable payments under Section 2(b) will not be paid before the first business day occurring after the sixtieth (60th) day following the Separation and, once they commence, will include any unpaid amounts accrued from the date of Executive's Separation (to the extent not otherwise satisfied with continuation coverage). However, if the period comprising the sum of the sixty (60)-day period described in the preceding sentence and the ten (10)-day period described in Section 7(e)(3) below spans two calendar years, then the payments which constitute deferred compensation subject to Section 409A will not in any case be paid in the first calendar year. Executive shall have no right to an additional gross-up payment to account for the fact that such COBRA premium amounts are paid on an after-tax basis.

3. **CIC Qualifying Termination.** If the Executive is subject to a CIC Qualifying Termination, then, subject to Sections 4, 9, and 10 below, Executive will be entitled to the following benefits:

(a) **Severance and Bonus Payments.** The Company or its successor shall pay the Executive (i) twelve (12) months of his or her monthly base salary (at the rate in effect immediately prior to the actions that resulted in the Separation) and (ii) a pro rata portion (based on number of months worked in the Company's fiscal year of the Separation) of Executive's then-current target bonus opportunity. Such payment shall be paid in a cash lump sum payment in accordance with the Company's standard payroll procedures, which payment will be made on the first business day occurring after the sixtieth (60th) day following the Separation, *provided that* the Release Conditions have been satisfied.

(b) **Equity.**

(i) **Post-IPO Equity Awards.** Each of Executive's then-outstanding Post-IPO Equity Awards, including awards that would otherwise vest only upon satisfaction of performance criteria, shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award. "**Post-IPO Equity Awards**" means all options to purchase shares of Company common stock that are granted on or after the Effective Date, as well as any and all other stock-based awards granted to the Executive, including but not limited to stock bonus awards, restricted stock, restricted stock units or stock appreciation rights that are granted on or after the Effective Date. Subject to Section 4, the accelerated vesting described above shall be effective as of the Separation.

(ii) **Pre-IPO Equity Awards.** For clarity, except as explicitly provided in Section 3(b)(iii) below, any options to purchase shares of Company common stock that were granted prior to the Effective Date, regardless of whether or not exercised prior to the Effective Date ("**Pre-IPO Equity Awards**" and, together with the Post-IPO Equity Awards, the "**Equity Awards**"), shall not be affected by or subject to

⁵ CFO

⁶ Executive officers who are not CEO or CFO

this Agreement, and such Pre-IPO Equity Awards shall continue to be governed by the vesting and acceleration provisions contained in the grant agreements for the Pre-IPO Equity Awards and, if applicable, any separate letter agreement pertaining to vesting acceleration of Pre-IPO Equity Awards entered into between the Company and Executive (such agreements, collectively, the "**Pre-IPO Equity Award Agreements**").

- (iii) **Non-Assumption of Equity Awards.** Notwithstanding anything to the contrary, if the successor or acquiring corporation (if any) of the Company refuses to assume, convert, replace or substitute Executive's unvested Equity Awards, as provided in Section 2.1.1 of the Plan, in connection with a Corporate Transaction (as defined in the Plan), then notwithstanding any other provision in this Agreement, the Plan or any Pre-IPO Equity Award Agreement to the contrary, each of Executive's then-outstanding and unvested Equity Awards that are not assumed, converted, replaced or substituted, including awards that would otherwise vest only upon satisfaction of performance criteria (measured at 100% of target), shall accelerate and become vested and exercisable as to 100% of the then unvested shares subject to the Equity Award effective immediately prior to the Corporate Transaction.

(c) **Pay in Lieu of Continued Employee Benefits.** If Executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("**COBRA**"), the Company or its successor shall pay the full amount of Executive's COBRA premiums on behalf of the Executive for the Executive's continued coverage under the Company's health, dental and vision plans, including coverage for the Executive's eligible dependents, for the twelve (12) month period following the Executive's Separation or, if earlier, until Executive is eligible to be covered under another substantially equivalent medical insurance plan by a subsequent employer. Notwithstanding the foregoing, if the Company, in its sole discretion, determines that it cannot provide the foregoing subsidy of COBRA coverage without potentially violating or causing the Company to incur additional expense as a result of noncompliance with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue the group health coverage in effect on the date of the Separation (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage, shall commence on the later of (i) the first day of the month following the month in which Executive experiences a Separation and (ii) the effective date of the Company's determination of violation of applicable law, and shall end on the earlier of (x) the effective date on which Executive becomes covered by a health, dental or vision insurance plan of a subsequent employer, and (y) the last day of the period twelve (12) months after the Separation, *provided that*, any taxable payments under Section 3(c) will not be paid before the first business day occurring after the sixtieth (60th) day following the Separation and, once they commence, will include any unpaid amounts accrued from the date of Executive's Separation (to the extent not otherwise satisfied with continuation coverage). However, if the period comprising the sum of the sixty (60)-day period described in the preceding sentence and the ten (10)-day period described in Section 7(e)(3) below spans two calendar years, then the payments which constitute deferred compensation subject to Section 409A will not in any case be paid in the first calendar year. Executive shall have no right to an additional gross-up payment to account for the fact that such COBRA premium amounts are paid on an after-tax basis.

4. **General Release.** Any other provision of this Agreement notwithstanding, the benefits under Section 2 and 3 shall not apply unless the Executive (i) has executed a general release (in substantially the form attached hereto as Exhibit A) of all known and unknown claims that he or she may then have against the Company or persons affiliated with the Company and such release has become effective and (ii) has agreed not to prosecute any legal action or other proceeding based upon any of such claims. The release must be in the form prescribed by the Company, without alterations (this document effecting the foregoing, the "**Release**"). The Company will deliver the form of Release to the Executive within thirty (30) days after the Executive's Separation. The Executive must execute and return the Release within the time period specified in the form.

5. **Accrued Compensation and Benefits.** Notwithstanding anything to the contrary in Section 2 and 3 above, in connection with any termination of employment (whether or not a Qualifying Termination or CIC Qualifying Termination), the Company shall pay Executive's earned but unpaid base salary and other vested but unpaid cash entitlements for the period through and including the termination of employment, including unused earned vacation pay and unreimbursed documented business expenses incurred by Executive through and including the date of termination (collectively "**Accrued Compensation and Expenses**"), as required by law and the applicable Company plan or policy. In addition, Executive shall be entitled to any other vested benefits earned by Executive for the period through and including the termination date of Executive's employment under any other employee benefit plans and arrangements maintained by the Company, in accordance with the terms of such plans and arrangements, except as modified herein (collectively "**Accrued Benefits**"). Any Accrued Compensation and Expenses to which the Executive is entitled shall be paid to the Executive in cash as soon as administratively practicable after the termination and, in any event, no later than two and one-half (2-1/2) months after the end of the taxable year of the Executive in which the termination occurs or at such earlier time as may be required by Section 10 below or to such lesser extent as may be mandated by Section 9 below. Any Accrued Benefits to which the Executive is entitled shall be paid to the Executive as provided in the relevant plans and arrangements.

6. **Covenants.**

(a) **Non-Competition.** The Executive agrees that, during his or her employment with the Company, he or she shall not engage in any other employment, consulting or other business activity (whether full-time or part-time) that would create a conflict of interest with the Company.

(b) **Cooperation and Non-Disparagement.** The Executive agrees that, during the six (6) month period following his or her cessation of employment, he or she shall cooperate with the Company in every reasonable respect and shall use his or her best efforts to assist the Company with the transition of Executive's duties to his or her successor. The Executive further agrees that, during this six-month period, he or she shall not in any way or by any means disparage the Company, the members of the Company's Board of Directors or the Company's officers and employees.

7. **Definitions.**

(a) **"Cause"** means: (i) Executive's conviction for, or guilty plea to, a felony involving moral turpitude; (ii) a willful refusal by Executive to comply with the lawful and reasonable instructions of the Company, or to otherwise perform Executive's duties as lawfully and reasonably determined by the Company, in each case that is not cured by Executive (if such refusal is of a type that is capable of being cured) within 15 days of written notice being given to Executive of such refusal; (iii) any willful act or acts of dishonesty undertaken by Executive and intended to result in Executive's (or any other person's) material gain or personal enrichment at the expense of the Company or any of its customers, partners, affiliates, or employees; or (iv) any willful act of gross misconduct by Executive which is injurious to the Company.

(b) **"Code"** means the Internal Revenue Code of 1986, as amended.

(c) **"Change in Control."** For all purposes under this Agreement, a Change in Control shall mean a "Corporate Transaction," as such term is defined in the Plan, *provided that* the transaction (including any series of transactions) also qualifies as a change in control event under U.S. Treasury Regulation 1.409A-3(i)(5).

(d) **"CIC Qualifying Termination"** means a Separation (i) within twelve (12) months following a Change in Control or (ii) within three (3) months preceding a Change in Control (but as to part (ii), only if the Separation occurs after a Potential Change in Control) resulting, in either case (i) or (ii), from (A) the Company or its successor terminating the Executive's employment for any reason other than Cause or (B) the Executive voluntarily resigning his or her employment for Good Reason. A termination or resignation due to the Executive's death or disability shall not constitute a CIC Qualifying Termination. A

"Potential Change in Control" means the date of execution of a legally binding and definitive agreement for a corporate transaction which, if consummated, would constitute the applicable Change in Control (which for the avoidance of doubt, would include a merger agreement, but not a term sheet for a merger agreement). In the case of a termination following a Potential Change in Control and before a Change in Control, solely for purposes of benefits under this Agreement, the date of Separation will be deemed the date the Change in Control is consummated.

(e) **"Good Reason"** means, without the Executive's consent, (i) a reduction in Executive's then-current base salary (except for a reduction that is part of a proportional reduction of the base salaries of all Company executives), bonus opportunity or commissions opportunity; (ii) the offices of the Company that Executive is required to report to being moved such that Executive's usual commuting distance is increased by more than ten (10) miles; or (iii) [a material and adverse change to Executive's duties or responsibilities, or if there is a change to Executive's title and role after which Executive does not have the title and role of Chief Financial Officer of the top-level acquiring entity whose stock is publicly traded]⁷ / [a material and adverse change to Executive's title, duties or responsibilities]⁸; provided, however, that a resignation by Executive shall not be considered to be for a "Good Reason" unless (i) Executive provides written notice to the Company's Chief Executive Officer of the occurrence of the event which Executive contends constitutes Good Reason within ninety (90) days of the date such event occurs, which notice states Executive's intention to resign for a "Good Reason" under this Agreement as a result thereof, (ii) the Company does not effect a cure with respect to such event within thirty (30) days of receipt of such written notice, and (iii) Executive thereafter resigns and ceases to perform services as an employee of the Company within ten (10) days of the expiration of the Company's cure period.

(f) **"Plan"** means the Company's 2016 Equity Incentive Plan, as may be amended from time to time.

(g) **"Release Conditions"** mean the following conditions: (i) Company has received the Executive's executed Release in substantially the form attached hereto as Exhibit A, and (ii) any rescission period applicable to the Executive's executed Release has expired.

(h) **"Qualifying Termination"** means a Separation that is not a CIC Qualifying Termination, but which results from (i) the Company terminating the Executive's employment for any reason other than Cause or (ii) the Executive voluntarily resigning his or her employment for Good Reason. A termination or resignation due to the Executive's death or disability shall not constitute a Qualifying Termination.

(i) **"Separation"** means a "separation from service," as defined in the regulations under Section 409A of the Code.

8. **Successors.**

(a) **Company's Successors.** The Company shall require any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets, by an agreement in substance and form satisfactory to the Executive, to assume this Agreement and to agree expressly to perform this Agreement in the same manner and to the same extent as the Company would be required to perform it in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets or which becomes bound by this Agreement by operation of law.

(b) **Executive's Successors.** This Agreement and all rights of the Executive hereunder shall inure to the benefit of, and be enforceable by, the Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

⁷ CFO

⁸ Executive officers who are not CEO or CFO

9. **Golden Parachute Taxes.**

(a) **Best After-Tax Result.** In the event that any payment or benefit received or to be received by Executive pursuant to this Agreement or otherwise ("**Payments**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this subsection (a), be subject to the excise tax imposed by Section 4999 of the Code, any successor provisions, or any comparable federal, state, local or foreign excise tax ("**Excise Tax**"), then, subject to the provisions of Section 10, such Payments shall be either (A) provided in full pursuant to the terms of this Agreement or any other applicable agreement, or (B) provided as to such lesser extent which would result in no portion of such Payments being subject to the Excise Tax ("**Reduced Amount**"), whichever of the foregoing amounts, taking into account the applicable federal, state, local and foreign income, employment and other taxes and the Excise Tax (including, without limitation, any interest or penalties on such taxes), results in the receipt by Executive, on an after-tax basis, of the greatest amount of payments and benefits provided for hereunder or otherwise, notwithstanding that all or some portion of such Payments may be subject to the Excise Tax. Unless the Company and Executive otherwise agree in writing, any determination required under this Section shall be made by independent tax counsel designated by the Company and reasonably acceptable to Executive ("**Independent Tax Counsel**"), whose determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required under this Section, Independent Tax Counsel may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code; *provided that* Independent Tax Counsel shall assume that Executive pays all taxes at the highest marginal rate. The Company and Executive shall furnish to Independent Tax Counsel such information and documents as Independent Tax Counsel may reasonably request in order to make a determination under this Section. The Company shall bear all costs that Independent Tax Counsel may reasonably incur in connection with any calculations contemplated by this Section. In the event that Section 9(a)(ii)(B) above applies, then based on the information provided to Executive and the Company by Independent Tax Counsel, Executive may, in Executive's sole discretion and within thirty (30) days of the date on which Executive is provided with the information prepared by Independent Tax Counsel, determine which and how much of the Payments (including the accelerated vesting of equity compensation awards) to be otherwise received by Executive shall be eliminated or reduced (as long as after such determination the value (as calculated by Independent Tax Counsel in accordance with the provisions of Sections 280G and 4999 of the Code) of the amounts payable or distributable to Executive equals the Reduced Amount). If the Internal Revenue Service (the "**IRS**") determines that any Payment is subject to the Excise Tax, then Section 9(b) hereof shall apply, and the enforcement of Section 9(b) shall be the exclusive remedy to the Company.

(b) **Adjustments.** If, notwithstanding any reduction described in Section 9(a) hereof (or in the absence of any such reduction), the IRS determines that Executive is liable for the Excise Tax as a result of the receipt of one or more Payments, then Executive shall be obligated to surrender or pay back to the Company, within one-hundred twenty (120) days after a final IRS determination, an amount of such payments or benefits equal to the "**Repayment Amount**." The Repayment Amount with respect to such Payments shall be the smallest such amount, if any, as shall be required to be surrendered or paid to the Company so that Executive's net proceeds with respect to such Payments (after taking into account the payment of the Excise Tax imposed on such Payments) shall be maximized. Notwithstanding the foregoing, the Repayment Amount with respect to such Payments shall be zero (0) if a Repayment Amount of more than zero (0) would not eliminate the Excise Tax imposed on such Payments or if a Repayment Amount of more than zero would not maximize the net amount received by Executive from the Payments. If the Excise Tax is not eliminated pursuant to this Section 9(b), Executive shall pay the Excise Tax.

10. **Miscellaneous Provisions.**

(a) **Section 409A.** To the extent (i) any payments to which Executive becomes entitled under this Agreement, or any agreement or plan referenced herein, in connection with Executive's termination of employment with the Company constitute deferred compensation subject to Section 409A of the Code and (ii) Executive is deemed at the time of such termination of employment to be a "specified" employee under

Section 409A of the Code, then such payment or payments shall not be made or commence until the earlier of (i) the expiration of the six (6)-month period measured from the Executive's Separation; or (ii) the date of Executive's death following such Separation; *provided, however*, that such deferral shall only be effected to the extent required to avoid adverse tax treatment to Executive, including (without limitation) the additional twenty percent (20%) tax for which Executive would otherwise be liable under Section 409A(a)(1)(B) of the Code in the absence of such deferral. Upon the expiration of the applicable deferral period, any payments which would have otherwise been made during that period (whether in a single sum or in installments) in the absence of this paragraph shall be paid to Executive or Executive's beneficiary in one lump sum (without interest). Except as otherwise expressly provided herein, to the extent any expense reimbursement or the provision of any in-kind benefit under this Agreement (or otherwise referenced herein) is determined to be subject to (and not exempt from) Section 409A of the Code, the amount of any such expenses eligible for reimbursement, or the provision of any in-kind benefit, in one calendar year shall not affect the expenses eligible for reimbursement or in kind benefits to be provided in any other calendar year, in no event shall any expenses be reimbursed after the last day of the calendar year following the calendar year in which Executive incurred such expenses, and in no event shall any right to reimbursement or the provision of any in-kind benefit be subject to liquidation or exchange for another benefit. To the extent that any provision of this Agreement is ambiguous as to its exemption or compliance with Section 409A, the provision will be read in such a manner so that all payments hereunder are exempt from Section 409A to the maximum permissible extent, and for any payments where such construction is not tenable, that those payments comply with Section 409A to the maximum permissible extent. To the extent any payment under this Agreement may be classified as a "short-term deferral" within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. Payments pursuant to this Agreement (or referenced in this Agreement) are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the regulations under Section 409A.

(b) **Other Arrangements.** This Agreement supersedes any and all cash severance arrangements and vesting acceleration arrangements on change in control under any agreement governing Equity Awards, severance and salary continuation arrangements, programs and plans which were previously offered, or may be offered on the Effective Date or thereafter, by the Company to the Executive, including change in control severance arrangements and vesting acceleration arrangements pursuant to an agreement governing Equity Awards, employment agreement or offer letter, and Executive hereby waives Executive's rights to such other benefits, provided that this Agreement shall not supersede the acceleration of vesting arrangements of any Pre-IPO Equity Awards (except as explicitly provided in Section 3(b)(iii) hereof). In no event shall any individual receive cash severance benefits under both this Agreement and any other vesting acceleration arrangement, severance pay or salary continuation program, plan or other arrangement with the Company, provided that this Agreement shall not supersede the acceleration of vesting arrangements of any Pre-IPO Equity Awards (except as explicitly provided in Section 3(b)(iii) hereof). For the avoidance of doubt, in no event shall Executive receive (i) payment under both Section 2 and Section 3 and/or (ii) acceleration of Equity Award vesting under both (a) Section 3(b)(iii) and (b) Section 3(b)(i) and/or Section 3(b)(ii), as applicable, in each case with respect to Executive's Separation.

(c) **Dispute Resolution.** To ensure rapid and economical resolution of any and all disputes that might arise in connection with this Agreement, Executive and the Company agree that any and all disputes, claims, and causes of action, in law or equity, arising from or relating to this Agreement or its enforcement, performance, breach, or interpretation, will be resolved solely and exclusively by final, binding, and confidential arbitration, by a single arbitrator, in San Diego County, and conducted by Judicial Arbitration & Mediation Services, Inc. ("**JAMS**") under its then-existing employment rules and procedures. Nothing in this section, however, is intended to prevent either party from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Each party to an arbitration or litigation hereunder shall be responsible for the payment of its own attorneys' fees.

(d) **Notice.** Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid or deposited with Federal Express Corporation, with shipping charges prepaid. In the case of the Executive, mailed notices shall be

addressed to him or her at the home address which he or she most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(e) **Waiver.** No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than the Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(f) **Withholding Taxes.** All payments made under this Agreement shall be subject to reduction to reflect taxes or other charges required to be withheld by law.

(g) **Severability.** The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(h) **No Retention Rights.** Nothing in this Agreement shall confer upon the Executive any right to continue in service for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Company or any subsidiary of the Company or of the Executive, which rights are hereby expressly reserved by each, to terminate his or her service at any time and for any reason, with or without Cause.

(i) **Choice of Law.** The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California (other than its choice-of-law provisions).

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

EXECUTIVE

OBALON THERAPEUTICS, INC.

[Name]

By:
Title:

EXHIBIT A

GENERAL RELEASE OF ALL CLAIMS AND COVENANT NOT TO SUE

This General Release of All Claims and Covenant Not to Sue (the "Release") is entered into between [Name of Executive] ("Executive") and Obalon Therapeutics, Inc. (the "Company") (collectively, "the parties").

WHEREAS, on _____, Executive and the Company entered into a Retention Agreement with the Company (the "Retention Agreement," to which this Release is attached as Exhibit A);

WHEREAS, on _____, Executive's employment with the Company terminated (the "Separation Date");

WHEREAS, this agreement serves as the Release, pursuant to the Retention Agreement; and

WHEREAS, Executive and the Company desire to mutually, amicably and finally resolve and compromise all issues and claims surrounding Executive's employment and separation from employment with the Company;

NOW THEREFORE, in consideration for the mutual promises and undertakings of the parties as set forth below, Executive and the Company hereby enter into this Release.

1. **Acknowledgment of Payment of Wages:** By his signature below, Executive acknowledges that, on the Separation Date, the Company paid him for all wages, salary, bonuses, commissions, reimbursable expenses, accrued but unused vacation and any similar payments due him from the Company as of the Separation Date. By signing below, Executive acknowledges that the Company does not owe him any other amounts, except as may become payable under the Retention Agreement and the Release.

2. **Return of Company Property:** Executive hereby warrants to the Company that he has returned to the Company all property or data of the Company of any type whatsoever that has been in his possession, custody or control.

3. **Consideration:** In exchange for Executive's agreement to this Release and his other promises in the Retention Agreement and herein, and pursuant to the Retention Agreement, the Company agrees to provide Executive with the consideration set forth in Section _____ of the Retention Agreement. By signing below, Executive acknowledges that he is receiving the consideration in exchange for waiving his rights to claims referred to in this Release.

4. **General Release and Waiver of Claims:**

a. The payments and promises set forth in this Release are in full satisfaction of all accrued salary, vacation pay, bonus and commission pay, profit-sharing, stock, stock options, restricted stock units or other ownership interest in the Company, termination benefits or other compensation to which Executive may be entitled by virtue of his employment with the Company or his separation from the Company, including pursuant to the Retention Agreement. To the fullest extent permitted by law, Executive hereby releases and waives any other claims he may have against the Company and its owners, agents, officers, shareholders, employees, directors, attorneys, subscribers, subsidiaries, affiliates, successors and assigns (collectively "Releasees"), whether known or not known, including, without limitation, claims under any employment laws, including, but not limited to, claims of unlawful discharge, breach of contract, breach of the covenant of good faith and fair dealing, fraud, violation of public policy, defamation, physical injury, emotional distress, claims for additional compensation or benefits arising out of his employment or separation of employment, including pursuant to the Offer Letter, claims under Title VII of the 1964 Civil Rights Act, as amended, the California Fair Employment

and Housing Act and any other laws and/or regulations relating to employment or employment discrimination, including, without limitation, claims based on age or under the Age Discrimination in Employment Act or Older Workers Benefit Protection Act, and/or claims based on disability or under the Americans with Disabilities Act.

b. By signing below, Executive expressly waives any benefits of Section 1542 of the Civil Code of the State of California, which provides as follows:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR."

c. Executive and the Company do not intend to release claims that he may not release as a matter of law, including but not limited to claims for indemnity under California Labor Code Section 2802, or any claims for enforcement of this Release. To the fullest extent permitted by law, any dispute regarding the scope of this general release shall be determined by an arbitrator under the procedures set forth in the Dispute Resolution section set forth in the Retention Agreement.

5. Covenant Not to Sue:

a. To the fullest extent permitted by law, at no time subsequent to the execution of this Release will Executive pursue, or cause or knowingly permit the prosecution, in any state, federal or foreign court, or before any local, state, federal or foreign administrative agency, or any other tribunal, of any charge, claim or action of any kind, nature and character whatsoever, known or unknown, which he may now have, have ever had, or may in the future have against Releasees, which is based in whole or in part on any matter released by this Release.

b. Nothing in this paragraph shall prohibit Executive from filing a charge or complaint with a government agency where, as a matter of law, the parties may not restrict his right to file such administrative complaints. However, Executive understands and agrees that, by entering into this Release, he is releasing any and all individual claims for relief, and that any and all subsequent disputes between Executive and the Company shall be resolved through arbitration as provided in the Retention Agreement.

c. Nothing in this paragraph shall prohibit or impair Executive or the Company from complying with all applicable laws, nor shall this Release be construed to obligate either party to commit (or aid or abet in the commission of) any unlawful act.

6. Review of Release: Executive understands that he may take up to twenty-one (21) days to consider this Release and, by signing below, affirms that he was advised to consult with an attorney prior to signing this Release. Executive also understands that he may revoke this Release within seven (7) days of signing this document and that the consideration to be provided to him pursuant to Paragraph 2(c) of the Retention Agreement will be provided only at the end of that seven (7) day revocation period.

7. Effective Date: This Release is effective on the eighth (8th) day after Executive signs it, provided he has not revoked it as of that time.

[Remainder of page intentionally left blank.]

8. Other Terms of Retention Agreement Incorporated Herein: All other terms of the Retention Agreement to the extent not inconsistent with the terms of this Release are hereby incorporated in this Release as though fully stated herein and apply with equal force to this Release, including, without limitation, the provisions on Non-Competition, Cooperation and Non-Disparagement, Section 409A, Dispute Resolution and Choice of Law.

Dated: _____

Name:
Title:
For the Company

Dated: _____

Name: [Name of Executive]

CERTIFICATION

I, Andrew Rasdal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Obalon Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or person performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2016

/s/ Andrew Rasdal

Andrew Rasdal

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

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) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or person performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2016

/s/ William Plovanic

William Plovanic
Chief Financial Officer
(Principal Financial Officer)

**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 period ended September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Rasdal, the President and Chief Executive Officer, and I, and William Plovanic, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 10, 2016

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

/s/ William Plovanic
William Plovanic
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.