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 June 30, 2020

or

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

Commission File Number: 001-37897

OBALON THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

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

(844) 362-2566
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

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

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

Total shares of common stock outstanding as of the close of business on July 18, 2020 was 7,731,633.

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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)

	June 30, 2020	December 31, 2019
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 6,804	$ 14,055
Accounts receivable, net	—	285
Inventory	—	1,936
Other current assets	3,971	1,959
Total current assets	10,775	18,235
Property and equipment, net	1,055	1,081
Lease right-of-use assets	748	1,077
Other long-term assets	1,295	—
Total assets	$ 13,873	$ 20,393
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,054	$ 648
Accrued compensation	240	820
Deferred revenue	123	424
Other current liabilities	3,603	1,524
Current portion of lease liabilities	579	561
Total current liabilities	5,599	3,977
Lease liabilities long-term	666	567
Long-term debt	430	—
Total long-term liabilities	1,096	567
Total liabilities	6,695	4,544
Commitments and contingencies (See Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 7,731,633 and 7,724,100 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	8	8
Additional paid-in capital	189,049	188,271
Accumulated deficit	(181,879)	(172,430)
Total stockholders' equity	7,178	15,849
Total liabilities and stockholders' equity	$ 13,873	$ 20,393

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	$ 703	$ 386	$ 1,483	$ 2,161
Cost of revenue	423	679	964	1,911
Gross profit (deficit)	280	(293)	519	250
Operating expenses:				
Research and development	765	1,788	2,022	4,227
Selling, general and administrative	2,362	4,332	6,255	10,536
Asset impairment and other charges	1,310	—	1,310	—
Total operating expenses	4,437	6,120	9,587	14,763
Loss from operations	(4,157)	(6,413)	(9,068)	(14,513)
Interest (expense) income, net	(5)	(295)	30	(485)
Other expense, net	(26)	(59)	(411)	(59)
Net loss and comprehensive loss	$ (4,188)	$ (6,767)	$ (9,449)	$ (15,057)
Net loss per share, basic and diluted	$ (0.54)	$ (2.52)	$ (1.22)	$ (6.02)
Weighted-average common shares outstanding, basic and diluted	7,728,624	2,687,829	7,726,915	2,500,619

See accompanying notes to unaudited interim condensed consolidated financial statements.

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

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2019	7,724,100	$ 8	$ 188,271	$ (172,430)	$ 15,849
Stock-based compensation	—	—	470	—	470
Vesting of stock awards, net of cancellations	7,533	—	—	—	—
Vesting of early exercised stock options	—	—	14	—	14
Net loss	—	—	—	(5,261)	(5,261)
Balance at March 31, 2020	7,731,633	8	188,755	(177,691)	11,072
Stock-based compensation	—	—	292	—	292
Vesting of early exercised stock options	—	—	2	—	2
Net loss	—	—	—	(4,188)	(4,188)
Balance at June 30, 2020	7,731,633	$ 8	$ 189,049	$ (181,879)	$ 7,178

See accompanying notes to consolidated financial statements.

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

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2018	2,351,333	$ 2	$ 161,859	$ (148,754)	$ 13,107
Stock-based compensation	—	—	1,105	—	1,105
Issuance of common stock for cash upon exercise of stock options	119	—	1	—	1
Vesting of early exercised stock options	—	—	14	—	14
Issuance of common stock, net of issuance costs	75,551	1	580	—	581
Cancellation of restricted stock awards	(2,051)	—	—	—	—
Net loss	—	—	—	(8,290)	(8,290)
Balance at March 31, 2019	2,424,952	3	163,559	(157,044)	6,518
Stock-based compensation	—	—	536	—	536
Issuance of common stock for cash upon exercise of stock options	—	—	—	—	—
Vesting of early exercised stock options	—	—	15	—	15
Issuance of common stock, net of issuance costs	1,158,187	1	8,073	—	8,074
Cancellation of restricted stock awards	(24,859)	—	—	—	—
Net loss	—	—	—	(6,767)	(6,767)
Balance at June 30, 2019	3,558,280	$ 4	$ 172,183	$ (163,811)	$ 8,376

See accompanying notes to consolidated financial statements.

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

	Six Months Ended June 30,	
	2020	**2019**
Operating activities:		
Net loss	$ (9,449)	$ (15,057)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	187	256
Stock-based compensation	762	1,641
Loss on disposal of fixed assets	—	95
Amortization of right-of-use assets	239	186
Accretion of investment discount, net	—	(2)
Amortization of debt discount	—	70
Impairment of long-lived assets and other charges	1,257	—
Impairment of inventory	53	—
Change in operating assets and liabilities:		
Accounts receivable, net	285	423
Inventory	(524)	(157)
Other current assets	(1,845)	1,760
Accounts payable	405	(191)
Accrued compensation	(564)	(2,712)
Deferred revenue	(302)	(32)
Lease liabilities, net	(147)	(136)
Other current and long-term liabilities	2,079	(142)
Net cash used in operating activities	(7,564)	(13,998)
Investing activities:		
Maturities of short-term investments	—	2,550
Purchases of property and equipment	(117)	(20)
Net cash (used in) provided by investing activities	(117)	2,530
Financing activities:		
Proceeds from long-term loan	430	10,000
Payment on long-term loan	—	(15,000)
Proceeds from issuance of common stock, net of issuance costs	—	8,793
Proceeds from sale of common stock upon exercise of stock options	—	1
Net cash provided by financing activities	430	3,794
Net decrease in cash and cash equivalents	(7,251)	(7,674)
Cash and cash equivalents at beginning of period	14,055	21,187
Cash and cash equivalents at end of period	$ 6,804	$ 13,513
Supplemental cash flow information:		
Interest paid	$ —	$ 563
Unpaid issuance costs	$ —	$ 377

See accompanying notes to unaudited interim condensed consolidated financial statements.

1. Organization and Basis of Presentation

Obalon Therapeutics, Inc., or the Company, was incorporated in the state of Delaware on January 2, 2008. The Company is a vertically-integrated medical device company focused on developing and commercializing innovative medical devices to treat obesity. Using its patented technology, the Company has developed the Obalon® balloon system, the first and only U.S. Food and Drug Administration, or FDA, approved swallowable, gas-filled intragastric balloon designed to provide progressive and sustained weight loss in obese patients.

The unaudited interim condensed consolidated financial statements include the accounts of Obalon Therapeutics, Inc., and its wholly owned subsidiary, Obalon Center for Weight Loss, Inc.

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

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

Reverse Stock Split

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

Liquidity

As of June 30, 2020, the Company has devoted a substantial portion of its efforts to product development, raising capital, and building infrastructure, and, since January 2017, U.S. commercialization. The Company has incurred operating losses and has experienced negative cash flows from operations since its inception. In July 2012, the Company realized initial revenue from its planned principal operations. The Company recognized total revenue of $0.7 million and $0.4 million for the three months ended June 30, 2020 and 2019, respectively, and $1.5 million and $2.2 million for the six months ended June 30, 2020 and 2019, respectively. Our revenue for the three months ended June 30, 2020 were primarily due to reversing various reserves related to revenue from customer incentive programs, swallow guarantee, and returns reserves as a result of stopping all commercial operations and underlying programs. However, the Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and has funded its activities to date almost exclusively from debt and equity financings.

As reflected in the accompanying condensed consolidated financial statements, the Company has a limited operating history and the sales and income potential of the Company's business are unproven. The Company has not been profitable since inception, and as of June 30, 2020, its accumulated deficit was $181.9 million. Since inception, the Company has financed its operations primarily through private placements of its preferred stock, the sale of common stock in its IPO and in subsequent public offerings and private placements, and, to a lesser extent, debt financing arrangements. As of June 30, 2020, the Company had cash and cash equivalents of $6.8 million. The Company expects to continue to incur net losses for the foreseeable future.

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. In late 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread globally. To date, COVID-19 has had, and will continue to have, an adverse impact on the Company's operations and expenses as a result of the preventive and precautionary measures that the Company, its customers, other businesses, and governments are taking, including the deferral of elective medical procedures and diversion of capital and other resources. In March 2020, the Company suspended all new patient treatments at its Obalon-branded retail centers due to the ongoing COVID-19 pandemic. The Company has taken further steps to significantly reduce expenses in an effort to extend its cash runway while it evaluates potential business options, strategic alternatives and the potential for third-party payor reimbursement that may be available when and if the current COVID-19 crisis stabilizes and the economy rebounds. The Company has significantly reduced the

organization to only essential personnel and expects that, after a transition at the end of July 2020, only two full-time employees will remain. All Obalon-branded retail centers have been shutdown with no intention to reopen, and the Company has halted plans for future retail center expansion. The Company does not expect to restart shipments to U.S. customers and has terminated the agreement with its international distributor, Al Danah Medical Company W.L.L. The decision to shift the Company's strategy to focus on pursuing reimbursement, while also evaluating other strategic options, occurred after the end of the first quarter of 2020. If the Company is unsuccessful in those two endeavors over the next several months, it may be forced to liquidate the business or pursue bankruptcy protection. As a result of the above factors, there is substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance date of the unaudited interim condensed consolidated financial statements for the three and six months ended June 30, 2020.

2. Summary of Significant Accounting Policies

There were no significant changes to the accounting policies during the six months ended June 30, 2020, from the significant accounting policies described in Note 2 of the “Notes to Consolidated Financial Statements” in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed on February 27, 2020.

Use of Estimates

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

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

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated financial statements as of June 30, 2020 and for the three and six months ended June 30, 2020 and 2019 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company’s condensed consolidated financial position as of June 30, 2020 and its condensed consolidated results of operations for the three and six months ended June 30, 2020 and 2019, statements of stockholders' equity for the three and six months ended June 30, 2020 and 2019, and cash flows for the six months ended June 30, 2020 and 2019. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period. The balance sheet as of December 31, 2019 included herein was derived from the audited financial statements as of that date. These financial statements should be read in conjunction with the Company’s audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed on February 27, 2020.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company’s comprehensive loss was the same as its reported net loss for all periods presented.

Fair Value Measurements

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

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

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

Concentrations of Credit Risk

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Customer A	— %	— %	16.2 %	— %
Customer B	— %	— %	— %	27.2 %
Customer C	5.8 %	50.5 %	3.0 %	20.6 %

	June 30, 2020	December 31, 2019
Accounts receivable:		
Customer A	— %	— %
Customer B	— %	— %
Customer C	— %	20.8 %

The Company's largest customer for the three and six months ended June 30, 2020 was New York Bariatric Group and Al Danah Medical Company W.L.L., respectively. The revenue from New York Bariatric Group for the three months ended June 30, 2020 related to certain reversals of prior revenue reserves and did not represent actual sales during the period. The largest customer for the three and six months ended June 30, 2019 was Bader Sultan & Bros. Co. W.L.L. There were no other international sales aside from sales to Al Danah Medical Company W.L.L. for the three and six months ended June 30, 2020.

Inventory

Inventory is stated at the lower of cost (which approximates actual cost on a first-in, first-out basis) or net realizable value, computed on a standard cost basis. Inventory that is obsolete or is in excess of forecasted usage is written down to its estimated net realizable value based on assumptions about future demand. Inventory write-downs are charged to cost of revenue and establish a new cost basis for the inventory.

The Company evaluated whether the shift in business strategy to pursue a reimbursement model was indicative of inventory impairment. The Company performed an impairment assessment on its inventory stock and recognized $0.1 million in impairment charges for the three months ended June 30, 2020 related to excess inventory not expected to be used in clinical trials to pursue reimbursement. The Company determined that the remaining inventory balance has an alternative future use in clinical trials and reclassified it to other current assets and other long-term assets. As a result, the Company does not have any inventory as of June 30, 2020.

Impairment of Long-Lived Assets

The Company evaluates property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount of the assets to the future undiscounted net cash flows, which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the difference between the carrying amount and the fair value of the impaired asset.

In light of the Company's shift in business strategy from the Obalon-branded retail treatment center model to a reimbursement model, the Company performed an impairment analysis on its long-lived assets and recognized $1.2 million in impairment charges for the three months ended June 30, 2020 relating to the assets as the Company's previous retail treatment centers.

Net Loss per Share

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

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

Recently Issued and Adopted Accounting Pronouncements

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

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted-average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The adoption of the new standard did not have a material impact on the Company's interim condensed consolidated financial statements.

Recently Issued Accounting Pronouncements not yet adopted

In June 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-13, Financial Instruments - Credit Losses, which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. In February 2020, the FASB issued ASU 2020-02, Financial Instruments-Credit Losses (Topic 326) and Leases (Topic 842) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases (Topic 842), which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2022. The Company believes the adoption will modify the way the Company analyzes financial instruments, but it does not anticipate a material impact on results of operations. The Company is in the process of determining the effects the adoption will have on its consolidated financial statements.

In December 2019, the FASB issued authoritative guidance intended to simplify the accounting for income taxes: ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. This guidance eliminates certain exceptions to the general approach to the income tax accounting model and adds new guidance to reduce the complexity in accounting for income taxes. This guidance is effective for annual periods after December 15, 2020, including interim periods within those annual periods. The Company is currently evaluating the potential impact of this guidance 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 June 30, 2020 and December 31, 2019 are as follows (in thousands):

		Fair value measurements at reporting date using		
	Balance as of June 30, 2020	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash	$ 724	$ 724		
Cash equivalents:				
Money market funds	6,080	6,080	$ —	$ —
Total assets	$ 6,804	$ 6,804	$ —	$ —

		Fair value measurements at reporting date using		
	Balance as of December 31, 2019	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash	$ 1,012	$ 1,012		
Cash equivalents:				
Money market funds	13,043	13,043		
Total assets	$ 14,055	$ 14,055	$ —	$ —

The Company’s investments in Level 1 assets are valued based on publicly available quoted market prices for identical securities as of June 30, 2020 and December 31, 2019.

Instruments Not Recorded at Fair Value on a Recurring Basis

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

4. Net Loss per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (4,188)	$ (6,767)	$ (9,449)	$ (15,057)
Weighted-average common shares outstanding, basic and diluted	7,728,624	2,687,829	7,726,915	2,500,619
Net loss per share, basic and diluted	$ (0.54)	$ (2.52)	$ (1.22)	$ (6.02)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Stock options to purchase common stock	—	—	—	112,892
Total	—	—	—	112,892

5. Balance Sheet Details

Inventory consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw materials	$ —	$ 1,835
Work in process	—	12
Finished goods	—	89
Total	$ —	$ 1,936

As noted in Note 2, the current economic environment along with the shift in business resulted in the Company reclassifying inventory to other current and long term assets as the Company has no intention to sell these assets but instead plans to use them for clinical trials. Additionally, the Company recorded an impairment charge of $0.1 million for the three months ended June 30, 2020 related to certain excess inventory.

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

	June 30, 2020	December 31, 2019
Prepaid expenses	$ 640	$ 1,890
Insurance receivable	3,150	—
Manufacturing use assets	166	—
Other assets	15	69
Total	$ 3,971	$ 1,959

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

	June 30, 2020	December 31, 2019
Computer hardware	$ 259	$ 263
Computer software	274	291
Leasehold improvements	427	497
Furniture and fixtures	179	247
Scientific equipment	1,968	1,999
Construction in progress, or CIP	406	110
	3,513	3,407
Less: accumulated depreciation	(2,458)	(2,326)
Total	$ 1,055	$ 1,081

Depreciation expense was $0.1 million for both the three months ended June 30, 2020 and 2019 and $0.2 million and $0.3 million for the six months ended June 30, 2020 and 2019, respectively. As noted in Note 2, the current economic environment along with the shift in business focus is an impairment triggering event for the other long-lived assets. This resulted in impairment and other charges of $1.3 million for the three months ended June 30, 2020. Based upon the Company's analysis, no other asset impairment charge was recorded.

Other long-term assets consists entirely of manufacturing use assets as of June 30, 2020.

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

	June 30, 2020	December 31, 2019
Accrued legal and professional fees	$ 93	$ 412
Accrued customer incentives	—	198
Accrued sales and other taxes	83	107
Returns reserve liability	—	315
Settlement accrual	3,150	—
Other accrued expenses	277	492
Total	$ 3,603	$ 1,524

6. Loan

Payroll Protection Program Loan

On April 22, 2020, the Company executed a promissory note (the “Note”) with Silicon Valley Bank (the “Lender”) evidencing an unsecured loan in the aggregate principal amount of $0.4 million (the “PPP Loan”), which was made pursuant to the Paycheck Protection Program (the “PPP”). The PPP was established under the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), which was enacted on March 27, 2020, and is administered by the U.S. Small Business Administration (“SBA”). All the funds under the PPP Loan were disbursed to the Company on April 23, 2020.

The Note provides for a fixed interest rate of one percent per year with a maturity date of April 22, 2022 (the “Maturity Date”). Monthly principal and interest payments due on the PPP Loan are deferred for a six-month period beginning from the date of disbursement of the PPP Loan. The PPP Loan may be prepaid by the Company at any time prior to the Maturity Date with no prepayment penalties or premiums. The Note contains customary event of default provisions.

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loans granted under the PPP. Such forgiveness will be subject to approval by the SBA and the Lender and determined, subject to limitations, based on factors set forth in the CARES Act, including verification of the use of loan proceeds for payment of payroll costs and payments of mortgage interest, rent and utilities. In the event the PPP Loan, or any portion thereof, is forgiven, the amount forgiven is applied to outstanding principal. The terms of any forgiveness may also be subject to further regulations and guidelines that the SBA may adopt. The Company will carefully monitor all qualifying expenses and other requirements necessary to attain loan forgiveness; however, no assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part.

As of June 30, 2020, the Company has used all proceeds from the PPP Loan to retain employees, maintain payroll and make lease and utility payments.

7. Stock-Based Compensation

Equity Incentive Plan

As of June 30, 2020, 1,012,669 stock options and awards remained available for future grant under the 2016 Equity Incentive Plan. No other plans had options or awards available for grant.

The Company recorded total non-cash compensation, including non-cash compensation to employees and nonemployees in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of revenue	$ —	$ (65)	$ 1	$ (26)
Research and development	59	191	157	410
Selling, general and administrative	233	410	604	1,257
Total	$ 292	$ 536	$ 762	$ 1,641

Unrecognized stock-based compensation expense at June 30, 2020 for all stock-based compensation pertaining to options was approximately $0.6 million, which is expected to be recognized over a weighted-average term of 2.5 years.

Incentive Stock Options

The following table summarizes stock option transactions for the 2016 Equity Incentive Plan for the six months ended June 30, 2020 (in thousands, except shares and per share data):

	Number of shares	Weighted-average exercise price per share	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2019	518,468	$ 38.64		
Options granted	463,000	0.80		
Options exercised	—	—		
Options canceled	(191,450)	30.03		
Outstanding at June 30, 2020	790,018	$ 18.55	8.36	$ —
Vested and expected to vest at June 30, 2020	693,494	$ 20.89	8.15	$ —
Vested and exercisable at June 30, 2020	284,649	$ 46.65	5.76	$ —

The weighted-average fair value of options granted during the six months ended June 30, 2020 was $1.12.

Restricted Stock Awards

The following table summarizes restricted stock award transactions for the 2016 Equity Incentive Plan for the six months ended June 30, 2020:

	Number of awards	Weighted-average grant date fair value
Outstanding at December 31, 2019	29,524	$ 39.64
Awards granted	—	—
Awards released	(26,524)	36.03
Awards canceled	—	—
Outstanding at June 30, 2020	3,000	$ 71.50

The Company's current restricted stock awards vest 100% at various terms from the grant date, subject to continued employment. The fair-value of each restricted stock award is determined on the grant date using the closing price of the Company's common stock on the grant date. Unamortized expense of $0.1 million is expected to be recognized over a weighted-average period of 1.0 year.

Restricted Stock Units

The following table summarizes restricted stock unit transactions for the 2016 Equity Incentive Plan for the six months ended June 30, 2020:

	Number of shares	Weighted-average grant date fair value	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2019	55,574	$ 11.70	
Awards granted	816,081	1.88	
Awards released	(8,696)	23.00	
Awards canceled	(816,081)	1.88	
Outstanding at June 30, 2020	46,878	$ 9.60	$ 33
Vested and expected to vest at June 30, 2020	46,470	$ 9.60	$ 33

The Company's current restricted stock units vest 100% at various terms from the grant date, subject to continued service. The fair-value of each restricted stock unit is determined on the grant date using the closing price of the Company's common stock on the grant date. An immaterial amount of unamortized expense is expected to be recognized over a weighted-average period of 0.1 years.

8. Stockholder's Equity

Public Offering and related warrants

On August 1, 2019, the Company entered into an underwriting agreement with A.G.P./Alliance Global Partners, as underwriter, in connection with a public offering of the Company's securities, pursuant to which the Company issued and sold (i) 2,427,500 shares of common stock (including 412,500 shares of common stock pursuant to the partial exercise of the underwriters' over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of common stock ("Pre-funded Warrants"), (iii) accompanying warrants to purchase up to 3,234,375 shares of common stock (including the exercise in full of the underwriters' over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) ("Purchase Warrants") and (iv) an additional warrant to the underwriters for the purchase 37,500 shares of common stock ("Representative Warrant"). The offering was made pursuant to a registration statement on Form S-1. The offering closed on August 6, 2019 resulting in gross proceeds of approximately $15.4 million. The Company incurred $0.7 million of legal, accounting, and other fees related to the offering. The shares of common stock and accompanying Purchase Warrants were sold at a public offering price of $4.00 per share, the Pre-funded Warrants and accompanying Purchase Warrants were sold at a public offering of $3.999. The Purchase Warrants were immediately exercisable upon issuance, will expire on August 6, 2024 and have an exercise price of $4.40 and the Representative Warrant has an exercise price of $5.00, in each case
subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events.

The Representative Warrant became exercisable in February 2020 and expires on August 6, 2024. All of the Pre-funded warrants were exercised during the third quarter of 2019. None of the Purchase or Representative Warrants have been exercised as of June 30, 2020. All of the warrants are recorded within equity in accordance with authoritative accounting guidance.

Lincoln Park Purchase Agreement

On February 5, 2020, the Company entered into a new purchase agreement (the "Purchase Agreement") and registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $15.0 million of the Company's common stock, $0.001 par value per share (the "Common Stock"). The new Purchase Agreement replaces an existing purchase agreement, dated December 27, 2018, by and between the Company and Lincoln Park, pursuant to which Lincoln Park committed to purchase up to $20.0 million of the Company's Common Stock. In connection with entering into the new Purchase Agreement, the Company and Lincoln Park terminated the prior purchase agreement, effective February 5, 2020.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of the Company's Common Stock. Such sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on February 28, 2020 date that a registration statement covering the resale of shares of Common Stock that have been and may be issued under the Purchase Agreement, which the Company agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement, was declared

effective by the SEC and a final prospectus in connection therewith was filed and the other conditions set forth in the purchase agreement were satisfied (such date on which all of such conditions are satisfied, the "Commencement Date").

The Company incurred approximately $0.3 million of legal, accounting, and other fees related to the offering. As of June 30, 2020 the Company has not sold any shares under the Purchase Agreement to Lincoln Park. The Company determined that there is a low probability that the equity line will be utilized for the remainder of 2020 due to adverse market circumstances. As a result, the Company fully expensed the $0.3 million of fees in March 2020.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following as of June 30, 2020:

Stock options issued and outstanding	790,018
Restricted stock units issued and outstanding	46,878
Warrants issued and outstanding	3,271,875
Authorized for future option and ongoing vesting of award grants	1,012,669
Authorized for future issuance under ESPP	190,222
Total	5,311,662

9. Income Taxes

For the three and six months June 30, 2020 and 2019, the Company did not record an income tax provision. The U.S. federal and California deferred tax assets generated from the Company's net operating losses have been fully reserved, as the Company believes it is more likely than not the benefit will not be realized.

10. Commitments and Contingencies

Operating Lease

The Company leases its facilities and retail treatment center under noncancelable operating leases which expire on various dates between 2022 and 2025. In July 2019, the Company entered into an office lease agreement to launch an Obalon-branded

retail treatment center in San Diego, California, which expires on August 5, 2021. In January 2020, the Company entered into lease agreements for two additional Obalon-branded retail treatment centers in Orange County, California and Sacramento, California, respectively. Under the terms of the facilities and retail center leases, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs. The treatment center leases in Sacramento and San Diego were terminated on April 29, 2020 and May 27, 2020, respectively as a result in the Company's shift in strategy away from the retail treatment center model in the second quarter of 2020. The Company has not paid rent under the Orange County lease or its lease for its headquarters in Carlsbad, since April 2020. The Company's landlord in Carlsbad, Gildred Development Company, has since sent a demand letter for rent. During the three months ended June 30, 2020, the Company recorded a $0.4 million charge to fully write off the Orange County right-of-use asset as the center will not be functioning.

Upon the Company's adoption of ASC 842 as of January 1, 2019, the Company recognized a ROU asset and lease liability for its building lease, assuming a 7.0% discount rate. Any short-term leases defined as 12 months or less or month-to-month leases were excluded and continue to be expensed each month. Total costs associated with short-term leases for the three months ended June 30, 2020 were immaterial.

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

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

The Company recorded an immaterial amount of lease liabilities, ROU assets, and interest expense associated with finance leases as of and for the three months ended June 30, 2020. The current and long-term portions of operating and finance lease liabilities are presented within the current portion of lease liabilities and lease liabilities long-term line items on the consolidated balance sheet, respectively. Operating and finance lease ROU assets are presented within the lease right-of-use assets line item on the consolidated balance sheet.

Future minimum annual lease payments under such leases were as follows as of June 30, 2020 (in thousands):

Operating leases:	
Remainder of 2020	$ 269
2021	564
2022	219
2023	105
2024	108
2025	37
Total undiscounted lease payments - operating leases	1,302
Finance leases:	
Remainder of 2020	12
2021	24
Total undiscounted lease payments - finance leases	36
Total undiscounted lease payments	1,338
Less: imputed interest	(93)
Lease liability	1,245
Less: current portion of lease liability	(579)
Lease liability, less current portion	$ 666

As of June 30, 2019, the Company’s remaining lease term ranges from 1.7 to 4.8 years. Rent expense totaled $0.1 million for both the three months ended June 30, 2020 and 2019 and $0.3 million and $0.2 million for the six months ended June 30, 2020 and 2019, respectively. The Company paid $0.1 million and $0.2 million of cash payments related to its operating lease agreement for the three and six months ended June 30, 2020, respectively. The Company's weighted average discount rate for leases as of June 30, 2020 was 6.0%.

Supplier Contracts

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

Shareholder Lawsuit

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against us and certain of our executive officers in the United States District Court for the Southern District of California (Hustig v. Obalon Therapeutics, Inc., et al., Case No. 3:18-cv-00352-AJB-WVG, and Cook v. Obalon Therapeutics, Inc. et al., Case No. 3:18-cv-00407-CAB-RBB). On July 24, 2018, the court consolidated the lawsuits and appointed Inter-Local Pension Fund GCC/IBT as lead plaintiff. On October 5, 2018, plaintiffs filed an amended complaint. The amended complaint alleges that we and certain of our executive officers made false and misleading statements and failed to disclose material adverse facts about our business, operations, and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of the Company’s initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation. On September 25, 2019, the court granted in part and denied in part the defendants’ motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims. On June 16, 2020, the parties reached a settlement of the securities class action, and they intend to submit a final settlement agreement for court approval. The settlement provides for a payment of $3.15 million to the plaintiffs, and provides that the defendants continue to deny the allegations and claims asserted by the plaintiffs, and are entering into the settlement solely to eliminate the burden and expense of further litigation. The Company expects that any amounts due as part of the settlement will be covered by the Company’s insurance policies.

As of June 30, 2020, the Company recorded a settlement accrual and corresponding insurance receivable for $3.15 million on the other current liabilities and other current assets lines on the condensed consolidated balance sheets, respectively.

11. Variable Interest Entity

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

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

For the six months ended June 30, 2020, the PC recognized $0.3 million of deferred revenue associated with prepaid services at the treatment center, which is fully presented in the condensed consolidated balance sheet of the Company at June 30, 2020.

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

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

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

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2019, included in our Annual Report on Form 10-K for the year ended December 31, 2019, filed on February 27, 2020.

OVERVIEW

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

The Obalon Balloon System is FDA approved for temporary use to facilitate weight loss in adults with obesity having a body mass index, or BMI, of 30 to 40, or approximately 30 to 100 pounds overweight, who have failed to lose weight through diet and exercise. The 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. We believe the Obalon Balloon System provides a cost-effective, non-surgical and reversible weight loss solution in an outpatient setting.

The Obalon Balloon System consists of a swallowable capsule that contains an inflatable balloon attached to a microcatheter; the Obalon Navigation System console, which is a combination of hardware and software used to track and display the location of the balloon during placement without x-ray; the Obalon Touch Inflation Dispenser, which is a semi-automated, hand-held inflation device used to inflate the balloon once it is placed; and a disposable canister filled with our proprietary mixture of gas. Placement of a balloon typically occurs in less than 15 minutes and can be accomplished in an outpatient setting without the

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

In clinical studies, the Obalon Balloon System has demonstrated clinically meaningful weight loss with durable results. In addition, data published and presented from our commercial registry demonstrates greater weight loss in the commercial setting as compared to our pivotal clinical study used to support FDA approval. In our published pivotal SMART trial, patients in the Obalon treatment group lost, on average, approximately twice as much body weight as patients in the sham-control group, with an average of 15.1 pounds of weight loss, resulting in an average 6.9% reduction in total body weight and an average 2.4 point decrease in BMI. 66.7% of patients lost at least 5% of their total body weight (%TBWL) and the study showed statistically significant improvements in cardiometabolic risk factors, including fasting glucose, systolic blood pressure, cholesterol and triglycerides. Patients in the treatment group were followed for 48 weeks and showed, on average, 89.5% of the weight loss achieved during the initial 24 week balloon treatment period was maintained at 48 weeks, or 24 weeks after the balloons were removed.

In December 2018, data from our commercial registry was analyzed, and later published and presented, on more than 1,300 patients at 108 treatment sites. For those patients who received three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in 9.9% reduction in total body weight and a 3.5 point decrease in BMI compared to baseline values. Of note, the top quartile of those patients lost an average of 39 pounds, resulting in an average of 16.8% reduction in total body weight and an average of a 6.2 point decrease in BMI compared to baseline values. Furthermore, in May 2019, analysis of data from our commercial registry was updated to include 1,411 total patients from 143 treatment sites in the United States. In this larger data set, for those patients receiving three balloons and at least 20 weeks of therapy, the average weight loss was 21.7 pounds, resulting in a 10.2% reduction in total body weight. Of note, 50.7% of patients lost 10% or more total body weight and 77.9% lost 5% or more total body weight.

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

When we commenced our U.S. commercial launch in 2017, we relied on a small direct sales force to sell our products directly to physicians, who would then sell weight loss treatment packages to their patients that included our balloon therapy, dietary counseling and balloon removal on a non-reimbursed, self-pay basis for patients. In 2019, we began implementing a fundamental change to our commercialization efforts, pursuant to which we eliminated our direct sales force and began establishing Company-owned or managed Obalon-branded retail treatments centers. We also transitioned to a centralized customer support model through which we sold to existing physician customers or new physicians that contacted us directly to acquire the Obalon Balloon System and provided centralized marketing and clinical support to those physicians.

In March 2020, we announced that the overall uncertainty, the restriction on elective procedures and the specific directives issued by the Governor of California as a result of COVID-19 had a significant impact on our business. As a result, we halted sales to new patients in our company-branded retail treatment centers, terminated expansion plans for additional retail centers and subsequently closed the two retail treatment centers we had opened. We have also halted manufacturing operations and have not filled orders to U.S. customers or our former international distributor since that time. Additionally, we terminated our contract with Al Danah, our only international distributor. In June 2020, we temporarily restarted manufacturing on a limited basis to convert our work in progress inventory to finished goods in order to have units available for clinical trials and unexpected physician sales but do not expect to continue manufacturing past June 30, 2020. Additionally, we expect that, after a transition at the end of July 2020, only two full-time employees will remain: Andy Rasdal, our President and Chief Executive Officer, and Nooshin Hussainy, our Chief Financial Officer.

Given those impacts and the significant concern about an economic recovery that would allow consumers to feel confident enough to spend on a cash-pay procedure like the Obalon Balloon System, we do not currently plan to re-open our retail treatment centers, re-initiate our retail treatment center expansion plans, or plan to ship orders to U.S. customers or our former international distributor. As a result, we would not expect to report any meaningful revenue for the foreseeable future.

We continue to believe the Obalon Balloon System can provide significant benefits to patients and value to the healthcare system. However, treatment with the Obalon Balloon System is not currently covered by any kind of private or public health insurance. We believe this has contributed to slow commercial adoption of the product and the procedure, as physicians are not reimbursed for treating patients with the Obalon therapy and patients must pay solely out of pocket for the Obalon Balloon System and the placement procedure. With that in mind, we are initiating efforts to explore obtaining third-party payor reimbursement and coverage for the Obalon Balloon System. We believe that reimbursement and coverage for the Obalon

Balloon System could significantly expand our market opportunity. There are more than 70 million adults in the United States who are obese and over 11 million adults in the United States who have Type 2 diabetes and are obese. Moreover, the COVID-19 pandemic has further highlighted the personal health and economics costs of the obesity epidemic in the United States. Recently published data suggest that next to age, the underlying health conditions of obesity and obesity-related health conditions (hypertension and diabetes) are the greatest predictors of COVID-19 hospitalizations and death. We believe the Obalon Balloon System could help reduce third-party payors' costs and improve patient care, and we intend to explore how additional data may be collected to demonstrate the economic and clinical evidence necessary to secure reimbursement. However, obtaining reimbursement is never certain and can take many years to achieve, and if achieved, may not be determinative of our success. If our initial efforts with payors begin to bear success, we would expect to need to raise additional capital to support those efforts.

To enable us to pursue this reimbursement strategy, we are taking further steps to significantly reduce expenses in an effort to extend our cash runway. We have significantly reduced the organization to only essential personnel. During this time we also plan to continue to explore other potential business options and strategic alternatives.

We generated total revenue of $0.7 million and $0.4 million for the three months ended June 30, 2020 and 2019, respectively, and $1.5 million and $2.2 million for the six months ended June 30, 2020 and 2019, respectively. We have incurred significant losses in each period since our inception in 2008, with net losses of $4.2 million and $6.8 million during the three months ended June 30, 2020 and 2019, respectively, and $9.4 million and $15.1 million during the six months ended June 30, 2020 and 2019, respectively. We have not been profitable since inception, and as of June 30, 2020, our accumulated deficit was $181.9 million. On April 22, 2020, we executed a promissory note in favor of Silicon Valley Bank evidencing an unsecured loan in the aggregate principal amount of $0.4 million, which was made pursuant to the Paycheck Protection Program and which we refer to as the PPP Loan. The Paycheck Protection Program was established under the Coronavirus Aid, Relief and Economic Security Act , which was enacted on March 27, 2020, and is administered by the U.S. Small Business Administration. All the funds under the PPP Loan were disbursed to us on April 23, 2020.

Our consolidated financial statements as of and for the three and six months ended June 30, 2020 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Based on our cash balances and recurring losses since inception, there is substantial doubt about our ability to continue as a going concern Our ability to continue as a going concern, and correspondingly to execute on our business plan and strategy, is dependent upon our ability to accomplish one or more of the following: raise additional capital in the very near term to fund our ongoing operations or engage in a strategic alternative. If we are not able to accomplish one or more of these goals in the near term, there is a high likelihood we may need to sell all or portions of our business, liquidate all or some of our assets or seek bankruptcy protection, which could result in significant decrease in value for all stakeholders.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Revenue

For the three and six months ended June 30, 2020 and 2019, revenue reflects sales of our Obalon Balloon System directly to physicians and institutions in the United States, sales of our Obalon Balloon System to our Middle East distributors, and sales from patients treated at our Company-managed Obalon-branded retail center. We also generated revenue during the six months ended June 30, 2020 from reversing various reserves related to revenue from customer incentive programs, swallow guarantee, and returns reserves as a result of terminating all commercial operations and underlying programs.

We do not currently plan to re-open our retail treatment centers, re-initiate our retail treatment center expansion plans, restart manufacturing operations, or plan to ship orders to U.S. customers or our former international distributor. As a result, we would not expect to report any meaningful revenue for the foreseeable future.

To date we have experienced limited penetration of the U.S. market, and there are many factors that may impact our future results of operations, including: our ability to establish coverage and reimbursement for the Obalon Balloon System, our ability to successfully develop the intragastric balloon market (which is currently small and immature) and gain acceptance of our current Obalon Balloon System and its future iterations by doctors and patients, our ability to scale production in a cost effective manner or if at all should we restart manufacturing operations, the emergence of competing products, actions by regulatory bodies, and general economic trends. The amount of revenue and timing of revenue recognition may also be impacted by any future com

mercial model and customer incentive programs we decide to offer and the channels through which the revenue is derived.

Cost of revenue and gross margin

Cost of revenue consists primarily of costs related to the direct materials and direct labor that are used to manufacture our products and the overhead costs that directly support manufacturing. Currently, a significant portion of our cost of revenue consists of manufacturing overhead, which is mostly fixed in nature. These overhead costs include the costs of compensation for operations management, engineering support, material procurement and inventory control personnel, outside consultants, production related supplies, allocated quality assurance and facilities costs, and depreciation on production equipment. In the foreseeable future, we expect cost of revenue to be higher than revenue as we focus on reimbursement activities rather than commercial sales.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, geographic mix, product mix, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect gross margin to fluctuate from quarter to quarter due to variability of our recognized revenue, our adoption of new manufacturing processes and technologies, changes in our manufacturing capacity, and discontinuation of obsolete products. We have experienced challenges in our ability to produce finished goods, which may impact our ability to meet the demands for future commercial and clinical trials.

In March 2020, we suspended manufacturing of the Obalon Balloon System due to the ongoing COVID-19 pandemic. We restarted manufacturing on a limited basis in June 2020 to convert a small amount of work-in-progress inventory to finished goods, in order to have units available for clinical trials and unexpected physician sales. As of June 30, 2020 our manufacturing operations have been suspended with no future plans for restarting.

Research and development expenses

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

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

We expense R&D costs as incurred. We expect R&D expenses for the third and fourth quarters of 2020 to be lower than historical averages due to the suspension of business operations. Going forward, we expect to incur R&D expenses associated with ongoing post-approval studies and with developing the clinical data needed to support reimbursement.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, commissions, benefits, travel expense and stock-based compensation expense. Other SG&A expenses include promotional and advertising activities, marketing, conferences and trade shows, professional services fees, including legal fees, accounting fees, insurance costs, general corporate expenses, and allocated facilities-related expenses. SG&A expenses decreased significantly starting in the second quarter of 2020 due to suspension of business operations and the reduction of employee personnel to only certain key employees. SG&A expenses are expected to remain significantly lower than historical averages until such time when business operations may resume.

Impairment Expense

In light of recent events associated with the global spread of COVID-19 and other factors, impairment expense was recognized for impairment of inventory and long-lived assets pertaining our retail operations during the second quarter of 2020.

RESULTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
Condensed consolidated statements of operations data:				
Revenue	$ 703	$ 386	$ 1,483	$ 2,161
Cost of revenue	423	679	964	1,911
Gross profit (deficit)	280	(293)	519	250
Operating expenses:				
Research and development	765	1,788	2,022	4,227
Selling, general and administrative	2,362	4,332	6,255	10,536
Asset impairment and other charges	1,310	—	1,310	—
Total operating expenses	4,437	6,120	9,587	14,763
Loss from operations	(4,157)	(6,413)	(9,068)	(14,513)
Interest (expense) income, net	(5)	(295)	30	(485)
Other expense, net	(26)	(59)	(411)	(59)
Net loss	(4,188)	(6,767)	(9,449)	(15,057)

Comparison of three months ended June 30, 2020 and 2019

Revenue. Revenue increased $0.3 million to $0.7 million during the three months ended June 30, 2020, compared to $0.4 million during the three months ended June 30, 2019. In the second quarter of 2020, we generated $0.1 million of revenue from the Obalon-branded retail treatment centers, and approximately $0.6 million of revenue from reversing various reserves related to revenues from customer incentive programs, swallow guarantee, and returns reserves as a result of terminating all commercial operations and underlying programs.

Cost of revenue and gross profit (deficit). Cost of revenue decreased $0.3 million to $0.4 million during the three months ended June 30, 2020, compared to $0.7 million during the three months ended June 30, 2019. The decrease in cost of revenue was primarily attributable to the decrease in operations compared to the prior year. Gross profit increased $0.6 million to $0.3 million during the three months ended June 30, 2020, compared to a gross deficit of $0.3 million during the three months ended June 30, 2019. The increase in gross profit was primarily due to the reversal of revenue reserves as a result of suspending all commercial operations during the second quarter of 2020.

Research and development expenses. R&D expenses decreased $1.0 million to $0.8 million during the three months ended June 30, 2020, compared to $1.8 million during the three months ended June 30, 2019. This decrease was due primarily to decreases in payroll related expenses of $0.6 million, outside consulting expenses of $0.2 million, clinical trial expenses of $0.1 million, and stock-based compensation expense of $0.1 million. R&D expenses for the three months ended June 30, 2019 included a restructuring charge of approximately $0.4 million.

Selling, general and administrative expenses. SG&A expenses decreased $1.9 million to $2.4 million during the three months ended June 30, 2020, compared to $4.3 million during the three months ended June 30, 2019. The decrease from the prior period was primarily driven by decreases in payroll related expenses of $0.9 million, outside consulting fees of $0.8 million, legal expense of $0.4 million, and stock-based compensation expense of $0.2 million. The decrease was offset by an increase of $0.4 million in insurance expenses. SG&A expenses for the three months ended June 30, 2019 included a restructuring charge of approximately $0.7 million.

Asset impairment expenses and other charges. Asset impairment expenses and other charges increased $1.3 million during the three months ended June 30, 2020, compared to zero during the three months ended June 30, 2019. This is due to the inventory and long-lived asset impairment charges recognized during the second quarter of 2020 as a result of our shift in business strategy away from the Obalon-branded retail center model to a reimbursement model strategy.

Interest (expense) income, net. Interest expense, net decreased $0.3 million to an immaterial amount during the three months ended June 30, 2020, compared to $0.3 million during the three months ended June 30, 2019. This decrease was attributable to the paying off all the outstanding debt on the Term Loan in the third quarter of 2019.

Other expense, net. Other expense, net decreased $0.1 million to zero during the three months ended June 30, 2020, compared to $0.1 million for the prior period. This decrease was attributable to various immaterial decreases in expenses.

Comparison of six months ended June 30, 2020 and 2019

Revenue. Revenue decreased $0.7 million to $1.5 million during the six months ended June 30, 2020, compared to $2.2 million during the six months ended June 30, 2019. The revenue decrease was due primarily to the suspension of operations and abandonment of the retail treatment model in the second quarter of 2020.

Cost of revenue and gross profit. Cost of revenue decreased $0.9 million to $1.0 million during the six months ended June 30, 2020, compared to $1.9 million during the six months ended June 30, 2019. This was primarily attributable to a decrease in production of products as we suspended operations and abandoned the retail treatment model in the second quarter of 2020. Gross profit increased $0.2 million to $0.5 million during the six months ended June 30, 2020, compared to $0.3 million during the six months ended June 30, 2019. This was primarily attributable to the reversal of revenue reserves during the second quarter of 2020, as a result of suspension of business operations.

Research and development expenses. R&D expenses decreased $2.2 million to $2.0 million during the six months ended June 30, 2020, compared to $4.2 million during the six months ended June 30, 2019. This decrease was due primarily to decreases in payroll related expenses of $1.0 million, supplies expense of $0.4 million, clinical trial expense of $0.3 million, facility allocation of $0.1 million, outside consulting of $0.2 million, and stock-based compensation expense of $0.2 million. R&D expenses for the three months ended June 30, 2019 included a restructuring charge of approximately $0.4 million.

Selling, general and administrative expenses. SG&A expenses decreased $4.2 million to $6.3 million during the six months ended June 30, 2020, compared to $10.5 million during the six months ended June 30, 2019. The decrease from the prior period was primarily driven by decreases of $1.8 million in payroll related expenses, $0.7 million in stock-based compensation due to a reduction in headcount, $0.7 million in accounting and legal fees, $0.5 million in spending on marketing and advertising programs, $0.3 million in travel expenses, $0.1 million in facility allocation, and $0.1 million in board of director expenses. SG&A expenses for the three months ended June 30, 2019 included a restructuring charge of approximately $0.7 million.

Asset impairment expenses and other charges. Asset impairment expenses and other charges increased $1.3 million during the six months ended June 30, 2020, compared to zero during the six months ended June 30, 2019. This is due to the inventory and long-lived asset impairment charges recognized during the second quarter of 2020 as a result of our shift in business strategy away from the Obalon-branded retail center model to a reimbursement model strategy.

Interest (expense) income, net. Interest (expense) income, net decreased $0.5 million to an immaterial amount during the six months ended June 30, 2020, compared to $0.5 million during the six months ended June 30, 2019. This decrease was attributable to paying off the Term Loan during the third quarter of 2019.

Other expense, net. Other expense, net increased $0.3 million to $0.4 million during the six months ended June 30, 2020, compared to $0.1 million for the prior period. This increase was attributable to increased equity issuance costs during the first six months of 2020 compared to the prior period.

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2020, we had cash and cash equivalents of $6.8 million and an accumulated deficit of $181.9 million. Our primary sources of capital have been private placements of our preferred securities, the sale of common stock in our initial public offering, or IPO, in October 2016, a subsequent private placement in August 2018, and various equity financings in 2019 including a follow-on offering in August 2019, and, to a lesser extent, debt financing arrangements. We are continuing to significantly reduce expenditures to extend our cash runway during the suspension of our business operations. We believe our current cash and cash equivalents as of June 30, 2020 are sufficient to fund our operations through the end of 2020.

In late 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread globally. To date, COVID-19 has had, and will continue to have, an adverse impact on our operations and expenses as a result of the preventive and precautionary measures that we, our customers, other businesses, and governments are taking, including the deferral of elective medical procedures and diversion of capital and other resources. In March 2020, we suspended all new patient treatments at our Obalon-branded retail centers due to the ongoing COVID-19 pandemic. We have taken further steps to significantly reduce expenses in an effort to extend our cash runway while we evaluates potential business options, strategic alternatives and the potential for third-party payer reimbursement that may be available when and if the current COVID-19 crisis stabilizes and the economy rebounds. We have significantly reduced the organization to only essential

personnel and expect that, after a transition at the end of July 2020, only two full-time employees will remain. All Obalon-branded retail centers have been shut down with no intention to reopen, and we have halted plans for future retail center expansion. We do not expect to restart shipments to U.S. customers and we have terminated the agreement with our international distributor, Al Danah Medical Company W.L.L. The decision to shift our strategy to focus on pursuing reimbursement, while also evaluating other strategic options, occurred after the end of the first quarter of 2020. As we reduce our personnel to two full time employees, we plan to continue to seek strategic alternatives that may be in the best interest of our stockholders, while we pursue third-party payor reimbursement and coverage for the Obalon Balloon System. If we are unsuccessful in those two endeavors over the next several months, there is a high likelihood we may need to liquidate all or some of our assets or seek bankruptcy protection which could result in significant decrease in value for all stakeholders.

As a result of the above factors, there is substantial doubt about our ability to continue as a going concern for the twelve months following the issuance date of the unaudited interim condensed consolidated financial statements for the three and six months ended June 30, 2020. The accompanying condensed consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

On April 22, 2020, we executed a promissory note in favor of Silicon Valley Bank evidencing an unsecured loan in the aggregate principal amount of $0.4 million, which was made pursuant to the Paycheck Protection Program and which we refer to as the PPP Loan. The Paycheck Protection Program was established under the Coronavirus Aid, Relief and Economic Security Act , which was enacted on March 27, 2020, and is administered by the U.S. Small Business Administration. All the funds under the PPP Loan were disbursed to us on April 23, 2020. The Note provides for a fixed interest rate of one percent per year with a maturity date of April 22, 2022 (the “Maturity Date”). Monthly principal and interest payments due on the PPP Loan are deferred for a six-month period beginning from the date of disbursement of the PPP Loan. The PPP Loan may be prepaid at any time prior to the Maturity Date with no prepayment penalties or premiums. The Note contains customary event of default provisions.

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loans granted under the PPP. Such forgiveness will be subject to approval by the SBA and the Lender and determined, subject to limitations, based on factors set forth in the CARES Act, including verification of the use of loan proceeds for payment of payroll costs and payments of mortgage interest, rent and utilities. In the event the PPP Loan, or any portion thereof, is forgiven, the amount forgiven is applied to outstanding principal. The terms of any forgiveness may also be subject to further regulations and guidelines that the SBA may adopt. We will carefully monitor all qualifying expenses and other requirements necessary to attain loan forgiveness; however, no assurance is provided that we will obtain forgiveness of the PPP Loan in whole or in part. We have used all proceeds to date from the PPP Loan to retain employees, maintain payroll and make lease and utility payments.

Public Offering

On August 1, 2019, we entered into an underwriting agreement with A.G.P./Alliance Global Partners, as underwriter, in connection with a public offering of our securities, pursuant to which we issued and sold (i) 2,427,500 shares of our common stock (including 412,500 shares of common stock pursuant to the partial exercise of the underwriters’ over-allotment option to purchase 562,500 additional shares), (ii) pre-funded warrants to purchase up to 1,735,000 shares of our common stock , (iii) accompanying warrants to purchase up to 3,234,375 shares of our common stock (including the exercise in full of the underwriters’ over-allotment option to purchase additional warrants to purchase 421,875 shares of common stock) and (iv) an additional warrant to the underwriters for the purchase of 37,500 shares of our common stock resulting in net proceeds from the offering of approximately $14.7 million after deducting underwriting discounts and commissions and offering expenses payable by us. Each share of common stock and each prefunded warrant was sold together with a purchase warrant entitling the holder to purchase 0.75 of a share of common stock. The common stock and accompanying purchase warrants were sold together at a public offering price of $4.00, and the pre-funded warrant and accompanying purchase warrants were sold at a public offering price of $3.999. The purchase warrants were immediately exercisable upon issuance, will expire on August 6, 2024 and have an exercise price of $4.40 and the underwriter warrant has an exercise price of $5.00 per share, in each case subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events. The underwriter warrant became exercisable in February 2020 and expires on August 6, 2024. All of the pre-funded warrants were exercised during the third quarter of 2019. None of the purchase or underwriter warrants have been exercised as of June 30, 2020.

Lincoln Park Purchase Agreement

On February 5, 2020, we entered into a new purchase agreement (the "Purchase Agreement") and registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $15.0 million of our common stock, $0.001 par value per share (the "Common Stock"). The new Purchase Agreement replaces an existing purchase agreement, dated December 27, 2018, by and between us and Lincoln Park, pursuant to which Lincoln Park committed to purchase up to $20.0 million of our Common Stock. In connection with entering into the new Purchase Agreement, we terminated the prior purchase agreement with Lincoln Park, effective February 5, 2020.

Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of our Common Stock. Such sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on February 28, 2020 date that a registration statement covering the resale of shares of Common Stock that have been and may be issued under the Purchase Agreement, which we agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement, was declared effective by the SEC and a final prospectus in connection therewith was filed and the other conditions set forth in the purchase agreement were satisfied (such date on which all of such conditions are satisfied, the "Commencement Date").

We incurred approximately $0.3 million of legal, accounting, and other fees related to the offering. As of June 30, 2020 we have not sold any shares under the Purchase Agreement to Lincoln Park. We determined that there is a low probability that the equity line will be utilized for the remainder of 2020 due to adverse market circumstances. As a result, we fully expensed the $0.3 million of fees in March 2020.

CASH FLOWS

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

	Six Months Ended June 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (7,564)	$ (13,998)
Investing activities	(117)	2,530
Financing activities	430	3,794
Net decrease in cash and cash equivalents	$ (7,251)	$ (7,674)

Net cash used in operating activities

During the six months ended June 30, 2020, net cash used in operating activities was $7.6 million, consisting primarily of a net loss of $9.4 million, and an increase in net operating assets of $0.6 million. These items were partially offset by non-cash charges of $2.4 million, consisting primarily of stock-based compensation expense and impairment of inventory and long-lived assets.

During the six months ended June 30, 2019, net cash used in operating activities was $14.0 million, consisting primarily of a net loss of $15.1 million, an increase in net operating assets of $1.2 million primarily related to a decrease in accrued compensation, partially offset by a decrease in other current assets. These items were partially offset by non-cash charges of $2.2 million, consisting primarily of stock-based compensation expense and depreciation expense.

Net cash (used in) provided by investing activities

During the six months ended June 30, 2020, net cash used by investing activities was $0.1 million, consisting primarily of capital expenditures.

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

Net cash provided by financing activities

During the six months ended June 30, 2020, net cash provided by financing activities was $0.4 million, consisting of proceeds from the Payroll Protection Program loan.

During the six months ended June 30, 2019, net cash provided by financing activities was $3.8 million, consisting primarily of proceeds from the draw down on the second tranche under our loan and security agreement with Pacific Western Bank of $10.0 million as well as proceeds from issuance of common stock, net of issuance costs of $8.8 million, partially offset by the payment on the loan with Pacific Western Bank of $15.0 million.

OFF-BALANCE SHEET ARRANGEMENTS

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies related to revenue recognition, accrued research and development costs, stock-based compensation expense and income taxes are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Operations included in the Annual Report on Form 10-K for the year ended December 31, 2019, filed on February 27, 2020.

RECENT ACCOUNTING PRONOUNCEMENTS

Except as described in Note 2 to our Unaudited Interim Condensed Consolidated Financial Statements under the heading "Recently Issued and Adopted Accounting Pronouncements", there have been no new accounting pronouncements or changes to accounting pronouncements during the six months ended June 30, 2020, as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed on February 27, 2020.

JOBS ACT ACCOUNTING ELECTION

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

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2020, 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 June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against us and certain of our executive officers in the United States District Court for the Southern District of California (Hustig v. Obalon Therapeutics, Inc., et al., Case No. 3:18-cv-00352-AJB-WVG, and Cook v. Obalon Therapeutics, Inc. et al., Case No. 3:18-cv-00407-CAB-RBB). On July 24, 2018, the court consolidated the lawsuits and appointed Inter-Local Pension Fund GCC/IBT as lead plaintiff. On October 5, 2018, plaintiffs filed an amended complaint. The amended complaint alleges that we and certain of our executive officers made false and misleading statements and failed to disclose material adverse facts about our business, operations, and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of the Company's initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation. On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims. On June 16, 2020, the parties reached a settlement of the securities class action, and they intend to submit a final settlement agreement for court approval. The settlement provides for a payment of $3.15 million to the plaintiffs, and provides that the defendants continue to deny the allegations and claims asserted by the plaintiffs, and are entering into the settlement solely to eliminate the burden and expense of further litigation. The Company expects that any amounts due as part of the settlement will be covered by the Company's insurance policies.

ITEM 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including our unaudited interim condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. The market price of our common stock would likely decline, and you could lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS

We have suspended or terminated essentially all of our commercial efforts, shut down our manufacturing operations and terminated nearly all of our employees, and we cannot assure you when, if ever, these efforts will recommence.

Our commercial operations expose us to risks associated with public health crises and outbreaks of epidemic, pandemic, or contagious diseases, such as the current outbreak of a novel strain of coronavirus (COVID-19). To date, COVID-19 has had, and is expected to continue to have, an adverse impact on our operations, including our product sales, manufacturing, supply chains, and our expenses, including as a result of preventive and precautionary measures that we, other businesses, and governments are taking. Largely as a result of the COVID-19 crisis, we have permanently closed our two Obalon-branded or managed retail weight loss centers, suspended future expansion plans for new retail centers, stopped shipping product to all U.S. customers, terminated our agreement with our only international distributor, and terminated our sales and marketing organizations. We have also shut down our manufacturing operations, including terminating all manufacturing and related support personnel. Most recently, we terminated all but a few essential employees. These terminations included key long-time senior executives and other functional personnel with deep knowledge and expertise important to our business that has been acquired and developed over many years. We do not expect to restart any of our operations unless we are able to secure reimbursement from third-party payors for our products and obtain adequate funding to continue operations and establish new

commercial relationships. We cannot assure you when, if ever, we will achieve any of these objectives and we do not expect to generate any revenue unless and until we can restart.

Even if we are able to obtain reimbursement and adequate funding to restart commercial operations, we would need to hire and train an entirely new workforce, including manufacturing, sales and marketing and administrative personnel. We would also need to requalify all aspects of our manufacturing operations. These efforts would take considerable time and we cannot assure you that we would be able to identify, hire and train sufficient personnel with the training and experience necessary to restart and operate the business.

There are many uncertainties regarding COVID-19, including governmental and public health responses and the unknown duration and extent of economic disruption. Due to the uncertainty surrounding COVID-19, we do not currently plan to re-open our retail treatment centers, re-initiate our retail treatment center expansion plans, restart manufacturing operations or to ship orders to U.S. customers or our former international distributor. Despite our efforts to manage and remedy these impacts on us, their ultimate impact also depends on factors beyond our knowledge or control, including the duration and severity of the COVID-19 outbreak as well as third-party actions taken to contain its spread and mitigate its public health effects. However, based on the current state of the pandemic in the United States and abroad, the disease has already disrupted our operations and had a material adverse effect on our business, results of operations, financial condition, cash flows and stock price, as well heightened many of the risks described elsewhere in the “Risk Factors” section of this Periodic Report on Form 10-Q.

We were unable to identify a strategic transaction that the board of directors believed to be in the best interest of stockholders

We engaged a financial advisor to identify and evaluate possible financial and strategic alternatives and their implications for us. We were unable to identify a strategic or financing transaction that the board of directors believed to be in the best interest of our stockholders. As a result, we may not have enough available cash to continue as an ongoing enterprise and there is a high likelihood we may need to sell all or portions of our business, liquidate all or some of our assets or seek bankruptcy protection which could result in significant decrease in value for all stakeholders.

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

Our operations have consumed substantial amounts of cash since inception. We have announced that we do not currently plan to re-open our Company-branded treatment centers, restart manufacturing operations, or ship orders to our U.S. customers or international distributor. As a result, we do not anticipate any material revenue for the foreseeable future. Additionally, we will continue to incur costs as a result of operating as a public company. The audit report of our independent registered public accounting firm covering the December 31, 2019 consolidated financial statements contains an explanatory paragraph that states that our recurring losses from operations and liquidity position raises substantial doubt about our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. To date, our operating losses have been funded primarily from outside sources of invested capital and gross profits.

The effects of COVID-19 on our business have also negatively impacted our liquidity position and operations, and have also contributed to the doubt about our ability to continue as a going concern. We cannot fully determine the extent to which COVID-19 may continue to impact our operations and liquidity position due to facts and circumstances that are beyond our knowledge or control. The perception that we may not be able to continue as a going concern may cause third parties including suppliers, customers, and employees to terminate their respective relationships with us due to concerns about our ability to meet our contractual obligations, which could have a material adverse effect on our business.

Our ability to continue as a going concern, and correspondingly to execute on our business plan and strategy, is dependent upon our ability to accomplish one or more of the following: raise additional capital in the very near term to fund our ongoing operations or engage in a strategic alternative. If we are not able to accomplish one or more of these goals in the near term, there is a high likelihood we may need to sell all or portions of our business, liquidate all or some of our assets or seek bankruptcy protection which could result in significant decrease in value for all stakeholders.

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

If we are not able to raise capital to meet our needs, we will not be able to support any ongoing operations and may not be able to settle all of our liabilities. We have actively reviewed financial and strategic alternatives, including debt and equity financing, whole or partial sale of the company and a reverse merger in order to meet our capital needs and financial obligations, and increase shareholder value, and to date we have been unable to identify a viable alternative for capital raising. As a result, adequate funding may not be available to us on acceptable terms, or at all.

In February 2020, we implemented a new purchase agreement with Lincoln Park Capital Fund, LLC, or Lincoln Park. Pursuant to the new purchase agreement with Lincoln Park, or the Lincoln Park Purchase Agreement, Lincoln Park has committed to purchase up to $15.0 million of our common stock from time to time over a 36-month period. The number of shares we may sell to Lincoln Park on any single business day in a Regular Purchase is 150,000, but that amount may be increased to up to 250,000 shares of our common stock, depending on the market price of our common stock at the time of sale and subject to a maximum limit of $1,000,000 per Regular Purchase. Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $15.0 million over the term of the Lincoln Park Purchase Agreement. In addition, under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding under the Lincoln Park Purchase Agreement unless we obtain stockholder approval or an exception pursuant to the rules of the Nasdaq Capital Market is obtained to issue more than 19.99%. This limitation will not apply in certain limited circumstances as set out in the Lincoln Park Purchase Agreement. We have not sold any shares to Lincoln Park in the first six months of 2020 under the current Purchase Agreement. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Global Market. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Park's beneficial ownership exceeding 9.99% of the then outstanding shares of our common stock. Given the limitations under this arrangement, we do not believe it is adequate to provide sufficient funds for us to continue as an on-going concern.

Even if we are able to raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders is likely to be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect existing stockholders' rights. Moreover, debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business.

If we are unable to obtain sufficient funds on acceptable terms or in a timely manner we will be forced to take additional actions, including attempting to sell all or portions of our business, liquidating all or some of our assets or seeking bankruptcy protection.

Our shift to a commercial strategy based on coverage and reimbursement by third-party payors may not be successful and will subject us to new risks, some of which we may not yet have identified.

We are currently developing a strategy to obtain coverage and reimbursement from third-party payors, which we believe could address one of the largest barriers to patient and physician adoption of the Obalon Balloon System. Historically, we have utilized both a direct to physician model and a Company-managed Obalon-branded retail treatment center strategy. Both of these commercial strategies utilized a patient cash-pay model, with varying degrees of success. We cannot assure you that this new strategy will be successful nor which delivery model to the patient will be utilized in the future should we be able to obtain coverage and reimbursement from third-party payors.

However, payors may refuse to provide coverage and reimbursement or 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. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Completion of clinical trials necessary to support coverage and reimbursement could take several years or more. We cannot provide any assurance that we will successfully, or in a timely manner, enroll clinical trials, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by third-party payors as sufficient to support coverage and reimbursement. Successful results of predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, one or more third-party payors may disagree with our analyses and interpretation of the data from any clinical trial we undertake, or may find the clinical trial design, conduct, monitoring, or results unreliable or inadequate to support coverage and reimbursement. If we are unable to develop the clinical support needed to establish coverage and reimbursement, we may be unable to sell our products.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Even if we are successful in obtaining coverage from third-party payors for the Obalon Balloon System or procedures using the product, physicians may not purchase the Obalon Balloon System if they do not receive sufficient reimbursement from these payors for the cost of the product or procedures using our product. If government and other third-party payors do not provide coverage or adequate reimbursement levels for the Obalon Balloon System or procedures using the product, the demand for the Obalon Balloon System will not increase and/or create additional pricing pressure for us, either of which could adversely impact our business and financial condition.

If we are unable to reestablish commercial operations, including sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we may not be successful in commercializing our products.

We terminated all of our commercial personnel and no longer have a functioning infrastructure for the sales, marketing, or distribution of any product, and the cost of reestablishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market our product, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services.

There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to regain customer confidence or recover market share that may have been ceded to competitors or other intragastric balloon technology;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs;
- the inability to negotiate with payors regarding reimbursement for our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we choose to enter into and maintain collaborative relationships for such sales, marketing and distribution capabilities, we would be highly dependent upon the collaborator’s strategic interest in our products, and that collaborator’s ability to successfully market and sell the product. To the extent that we depend on third parties for marketing and distribution, any revenue we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our products and may not become profitable. We may be competing with many companies that have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these companies.

We have received funding under the Coronavirus Aid, Relief and Economic Security (CARES) Act

On April 22, 2020, we executed a promissory note in favor of Silicon Valley Bank evidencing an unsecured loan in the aggregate principal amount of $0.4 million, which was made pursuant to the Paycheck Protection Program, or the PPP. The PPP was established under the CARES Act, which was enacted on March 27, 2020, and is administered by the U.S. Small Business

Administration, or the SBA. All the funds under the loan were disbursed to us on April 23, 2020. The Company has used all proceeds from the loan to retain employees, maintain payroll and make lease and utility payments.

The promissory note provides for a fixed interest rate of one percent per year with a maturity date of April 22, 2022. Monthly principal and interest payments due on the loan are deferred for a six-month period beginning from the date of disbursement. The loan may be prepaid by the Company at any time prior to April 22, 2022 with no prepayment penalties or premiums.

Under the terms of the CARES Act, loan recipients can apply for and be granted forgiveness for all or a portion of the loans granted under the PPP. Such forgiveness will be subject to approval by the SBA and the lender and determined, subject to limitations, based on factors set forth in the CARES Act, including verification of the use of loan proceeds for payment of payroll costs and payments of mortgage interest, rent and utilities. In the event the loan, or any portion thereof, is forgiven, the amount forgiven is applied to outstanding principal. The terms of any forgiveness may also be subject to further regulations and guidelines that the SBA may adopt. If the loan is not forgiven, we will be required to repay the outstanding principal, along with accrued interest. The Company will carefully monitor all qualifying expenses and other requirements necessary to attain loan forgiveness; however, no assurance is provided that the Company will ultimately apply for or obtain forgiveness of the PPP loan in whole or in part.

The PPP loan application required us to certify, among other things, that the current economic uncertainty made the PPP loan request necessary to support our ongoing operations. On April 23, 2020, the SBA, in consultation with the Department of Treasury, issued new guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. We made the certification in good faith after analyzing our financial situation and access to capital and believe that we have satisfied all eligibility criteria for the PPP loan, but the SBA guidance and criteria is subject to interpretation and if we are found to be ineligible, we could be subject to significant penalties and required to repay the loan. If we become subject to penalties or are not able to attain loan forgiveness, it could result in harm to our business, results of operation and financial condition.

We have limited operating experience and a history of net losses, and we recently discontinued all of our commercial operations.

We have a limited operating history upon which you can evaluate our business and we recently discontinued all of our commercial operations while we explore our ability to secure coverage and reimbursement for our products and other strategic alternatives. Prior to discontinuing our commercial operations, we had marketed our products only since January 2017 and our commercial sales experience has been limited. We have incurred significant losses in each period since our inception in 2008, with net losses of $4.2 million and $6.8 million during the three months ended June 30, 2020 and 2019, respectively, and $9.4 million and $15.1 million during the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of approximately $181.9 million and had cash and cash equivalents of $6.8 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop, seek and obtain regulatory approval for our current and future generation Obalon Balloon System and sell our Obalon Balloon System in international and U.S. markets, and commercialize our Obalon Balloon System in the United States. Our consolidated financial statements as of and for the three month period ended June 30, 2020 have been prepared on the basis that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Based on our cash balances and recurring losses since inception, there is substantial doubt about our ability to continue as a going concern and if we are not able to raise additional capital in a timely manner, we will not be able to support our ongoing operations.

While we explore potential alternatives for obtaining coverage and reimbursement for our products, we have dramatically reduced our costs and expenses. These costs and expenses may increase significantly if we determine to pursue additional clinical trials that may be needed to secure reimbursement. If we secure reimbursement and return to commercial operations, we would expect our costs and expenses to increase substantially as we rebuild our sales and marketing and manufacturing capabilities. As a public company, we will continue to incur significant insurance, legal, accounting, compliance and other expenses, and we expect our losses to continue for the foreseeable future. Unless and until we return to commercial operations, we do not expect to generate any revenue. We cannot assure you when, if ever, we will generate revenue and, if we do, whether we will ever achieve profitability.

Our business is entirely dependent on sales of the Obalon Balloon System, which we are currently not marketing or selling.

All of our revenue to date was attributable to sales of our Obalon Balloon System including its component parts and accessories. In 2020, largely due to the COVID-19 crisis, we discontinued all of our commercial operations while we explore

our ability to secure coverage and reimbursement for our products and other strategic alternatives. Even if we are able to secure reimbursement for the Obalon Balloon System and restart commercial operations, there are a number of factors that may contribute to our financial results, including:

- patient interest in and demand for our Obalon Balloon System;
- our ability to maintain adequate coverage and reimbursement for the Obalon Balloon System;
- positive or negative media coverage, or public, patient and/or physician perception, of our Obalon Balloon System, the procedures or products of our competitors, or our industry;
- any safety or efficacy concerns that arise through physician and patient experience with our Obalon Balloon System;
- any safety or efficacy concerns for the category of intragastric balloons, including liquid-filled balloons, as the FDA has issued four Letters to Health Care Providers warning them about the use of liquid-filled intragastric balloons citing potential risks, including death;
- our ability to service and maintain equipment such as the Obalon Navigation System;
- delays in, or failure of, product and component deliveries by our third-party suppliers and single-source suppliers;
- willingness of physicians to purchase the capital equipment required to place balloons using the Obalon Navigation System;
- difficulties in producing a sufficient quantity of our product to meet commercial demand due to shortages of component parts or due to issues in the manufacturing process;
- introduction of new procedures or products for treating patients who are obese or overweight that compete with our product;
- adverse changes in the economy that reduce patient demand for elective procedures; and
- favorable or unfavorable positions developed on intragastric balloons, or the Obalon Balloon System by professional medical associations, such as the American Society for Metabolic and Bariatric Surgery (ASMBS), the American Society for Gastrointestinal Endoscopy (ASGE), or other organizations with influence on physicians.

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

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

We have historically maintained a high level of inventory, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges especially if we restart commercial operations and manufacturing in the future.

We are a vertically integrated manufacturer and insufficient demand for our products subjects us to risks. As a result of the need to maintain substantial levels of inventory due to single third-party sourcing and long lead-times to develop alternate third-party sources, we historically carried a high level of inventory for strategic materials. Due to the suspension of our business operations, we have ceased shipping product to U.S. and international customers, closed our Obalon-branded retail treatment centers and halted expansion of our retail treatment center model. We performed an impairment analysis and recognized $1.3 million in asset impairment and other charges during the second quarter of 2020. If we are not successful executing clinical trials for reimbursement in the future then further impairments may be recognized, which will have a material adverse effect on our future earnings and cash flows.

We have ongoing lease obligations under two non-cancelable long-term leases and we may not be able to meet our obligations under these agreements.

We have long-term lease obligations related to our headquarters and manufacturing space in Carlsbad and for one Obalon-branded retail treatment center in Orange County, California. We have not paid rent for our Carlsbad facility or Orange County retail treatment center since April 2020 and have notified both owners that we are taking advantage of the protections we believe are afforded by the relevant mandates related to the COVID-19 crisis. We have received a demand letter for payment of rent by the owner of our Carlsbad facility. With rent payments being delayed, our landlords may at their option (a) terminate our headquarters and manufacturing leases or could take other actions that restrict our ability to operate the business, including requesting damages for the Carlsbad lease, or (b) keep the lease in place and continue to have the right to collect rent as and when it becomes due for the remainder of the term of such lease.

Physicians have been 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 patient adoption. If any of these events were to occur, our prospects would be negatively affected.

Intragastric balloons represent a relatively new category of treatment for obese and overweight patients that is small, immature and not currently covered or reimbursed by third-party payors. We are currently aware of only one other intragastric balloon available for commercial sale in the United States, which was first commercially available in 2015. As a result, patient and physician awareness of intragastric balloons as a treatment option for obesity and weight management, and experience with intragastric balloons, is minimal. Prior to discontinuing our commercial operations, we experienced limited penetration of this market, and any future success will depend in large part on our ability to obtain coverage and reimbursement, to further develop the currently small and immature intragastric balloon market, educate physicians and patients, and to successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other merits of our Obalon Balloon System.

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 may attribute such negative events to intragastric balloons generally, which may adversely affect market adoption of our Obalon Balloon System. Since February 2017, the FDA has issued four separate letters to health care providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. We are aware of the filing of additional reports of serious adverse events, including deaths, associated with liquid-filled balloons since the issuance of the FDA safety alert letters. While the alerts were specific to liquid-filled intragastric balloons, not gas-filled intragastric balloons, these alerts could create negative perceptions of the entire category and slow down the acceptance of the Obalon Balloon System. Medical professional associations, such as ASMBS, have or may publish positions to their memberships which may be favorable or unfavorable toward the use of intragastric balloons, or the Obalon Balloon specifically. Additionally, if patients undergoing treatment with our Obalon Balloon System perceive the weight loss inadequate or adverse events too numerous or severe as compared with the treatment rates of alternative balloons or procedures, it will be difficult to demonstrate the value of our Obalon Balloon System to patients and physicians. As a result, demand for our Obalon Balloon System may decline or may not increase at the pace or to the levels we expect.

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

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

If patients are unable to successfully swallow the capsule or our balloon cannot otherwise be successfully deployed, patients may seek a refund or monetary damages in connection with the treatment.

Patients may be unable to successfully swallow the capsule that contains the Obalon balloon, potentially creating an economic disincentive for physicians to prescribe the Obalon Balloon System. In our SMART pivotal trial, 7.6% of the combined treatment and control group patients failed to swallow a capsule with the microcatheter attached despite success swallowing a

placebo that did not have a catheter attached. We are experiencing similar rates in U.S. commercial usage. There have also been instances where balloon deployment was negatively impacted due to a leak in the microcatheter caused by the patient biting the catheter during placement and requiring endoscopic removal. There may be other reasons for unsuccessful placements of which we are not yet aware. If the balloon is not successfully placed for any reason, the patient may attempt to seek a refund or monetary damages for the treatment. Either scenario could cause a negative financial impact for us and could also create ill will with patients and physicians.

Additionally, patients may seek a refund or monetary damages from us due to Company-branded treatment center closures, inability to complete treatment, persistent side-effects resulting in early removal, and general discontent with outcomes.

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

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

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

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

In the past we have, and in the future we may actively employ social media and call center activities as part of our marketing strategy, which could give rise to regulatory violations, liability, breaches of data security or reputational damage.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable laws and regulations, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA, CMS and Federal Trade Commission. For example, adverse events, product complaints, off-label usage by

physicians, unapproved marketing or other unintended messages could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill.

We have limited experience manufacturing our Obalon Balloon System and Obalon Navigation System in commercial quantities and, if we restart manufacturing may experience production delays or issues in our manufacturing organization and be unable to meet current or future demand.

Prior to 2017, the majority of our product sales had been to a single international distributor in the Middle East. We first sold our products to physicians and institutions in the United States in 2017, and we anticipate the United States to be our primary market focus going forward. We have limited experience in manufacturing the current Obalon Balloon System and all its related components in commercial quantities. Moreover, we recently terminated our existing manufacturing capabilities, and if we determine to restart commercial operations, we will need to reestablish those capabilities, and likely improve them, in order to satisfy expected demand. We may find that we are unable to successfully manufacture our products in sufficient quantities, on a timely basis and with the expected quality. Any failure to meet the quality, quantity and timeliness expectations of our customers could negatively impact our results of operations.

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

- the termination of our manufacturing organization and related support functions and/or ability to successfully rehire the necessary talent and capabilities;
- 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, especially as we have not placed any future orders from those supplies;
- production delays or stoppages caused by receiving components or supplies which do not meet our quality specifications;
- delays that we may experience in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;
- delays that we may experience in seeking FDA review and approval of PMA supplements required for certain changes in manufacturing facilities, methods or quality control procedures;
- our limited experience in complying with the FDA's Quality System Regulation, or the QSR, which sets forth good manufacturing practice requirements for medical devices and applies to the manufacture of the components of our Obalon Balloon System;
- our ability to attract, train, and retain qualified employees, who are in short supply, in order to increase our manufacturing output;
- our ability to design and validate processes to allow us to manufacture future generations of the Obalon Balloon System that meets or exceeds our quality specifications in an efficient, cost-effective manner;
- our ability to produce commercial product that meets or exceeds our manufacturing specifications and release criteria;
- production delays or stoppages caused by malfunction of production equipment and/or malfunction of the electrical, plumbing, ventilation, or cooling systems supporting our manufacturing facility; and
- production stoppages and/or product scrap caused by positive tests for objectionable organisms on our products.

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.

Historically, we manufactured our Obalon Balloon System and some of its components and sub-assemblies at our Carlsbad facility, and we relied on third-party suppliers for other components and sub-assemblies used in production. In some cases, these suppliers were single source suppliers. For example, we relied on single suppliers for the extruded film, swallowable capsule, molded silicone valve used to manufacture our Obalon balloons and the hydrophilic coating for our catheters. We also relied on additional single source suppliers for components of our Obalon Navigation balloons and console, including sensors. These components are critical to our current and future products and there are relatively few alternative sources of supply. We

do not carry a significant inventory of these components and obtaining additional components may require significant lead-time. We have experienced and may continue to experience production challenges due to shortages of key components from suppliers.

Moreover, we have not placed any future orders with our suppliers and they could refuse to fill future orders in the event we restart manufacturing, they may lose the capabilities to produce for us or they may refuse to do business with us at all in the future. 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 our ability to restart production and, going forward, could adversely affect our ability to fill product orders, service and maintain equipment with customers. For example, given that our Obalon Balloon System is a PMA approved product, any replacement supplier will have to be assessed by us through audits and other verification and assessment tools and found capable of producing quality components that meet our approved specifications, and we may be required to notify or obtain approval from the FDA for a change in a supplier prior to our ability to use the components it provides. If we were unable to find a replacement supplier, it could result in significant delays as we would be unable to produce additional product until such replacement supplier had been identified and qualified. If an existing or replacement supplier proposes to change any component specifications or quality requirements, the change may require FDA approval of a PMA supplement. If a supplier changes a component without notifying us, that change could result in an undetected change being incorporated into the finished product. Once detected and investigated, if the change is found to potentially affect the safety or effectiveness of the product, we would have to take corrective and preventive action, including possibly recalling the product, which could be time-consuming and expensive, and could impair our ability to meet the demand of our customers and harm our business and reputation.

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

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

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

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

Al Danah Medical Company W.L.L, or Al Danah, was the sole distributor of our Obalon Balloon System in the Middle East and our sole international customer. International sales to Al Danah represented 0% of our total revenue for the three months ended June 30, 2020 and 2019, and 16.2% and 0% for the six months ended June 30, 2020 and 2019, respectively. Bader Sultan & Bros. Co. W.L.L., or Bader, was previously the sole distributor of our prior generation Obalon balloon system in the Middle East and our sole international customer. The agreement with Bader was terminated in December 2019. In May 2020 we terminated the agreement with Al Danah and will not ship them product in the future. The significant reduction in international revenue in 2020 has had a significant impact on our financial performance. Currently, we do not have regulatory approval for our Obalon Navigation System and Obalon Touch Inflation Dispenser in the Middle East. However, there are certain countries in the Middle East that allow importation of medical device products with United States FDA approval or clearance to meet local regulatory standards, including Qatar.

If we were to restart commercial operations, we would not intend to devote significant additional resources in the near-term to market our Obalon Balloon System internationally, which will limit our potential revenue from our product.

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

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

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

In the United States, our product competes with a variety of pharmaceuticals, surgical procedures and devices for the treatment of obese and overweight people. There are several competitors in the pharmaceutical segment including Vivus, Inc., Eisai Co., Ltd, Inc., AstraZeneca plc, and Allergan plc. Large competitors in the surgical segment for weight loss and obesity include Ethicon Inc. (subsidiary of Johnson & Johnson), Medtronic plc (formerly Covidien Ltd.), Apollo EndoSurgery, Inc., and ReShape LifeSciences (which acquired the Lap-Band from Apollo Endosurgery, Inc. and currently sells that device worldwide). We are aware of only one FDA approved, commercially marketed liquid-filled balloon device for treating overweight people, the ORBERA Balloon by Apollo EndoSurgery. Outside of the United States, Allurion Technologies, Inc. has developed a swallowable, passable liquid-filled intragastric balloon that has been approved for sale in Europe and the Middle East and completed enrollment in a U.S. clinical trial and is pending FDA approval. Spatz Medical has also developed a liquid-filled intragastric balloon that has been approved for sale in Latin America and Europe and is is currently under review by the FDA for PMA approval. We also compete against non-balloon treatments including Aspire Bariatrics' ApireAssist device and a

technology developed by Gelesis known as the Plenity device, that is intended to expand in the stomach by absorbing water to create the feeling of satiety. Gelesis's Plenity device was cleared by FDA in 2019. Also in 2019, BAROnova gained FDA PMA approval in the U.S. for its transpyloric shuttle, a non-surgical, non-pharmacologic device to induce weight loss by slowing gastric emptying. Additionally, we are aware of numerous companies around the world working to develop less invasive and less costly alternatives for the treatment of obesity, any of which, if approved, could compete with us in the future.

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

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

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

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

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

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

We have not paid rent for our Carlsbad facility since April 2020 and have notified the owner that we are taking advantage of the protections we believe are afforded by the relevant mandates related to the COVID-19 crisis. We have received a demand letter for payment of rent by the owner of our Carlsbad facility. We could be required to move manufacturing to another location in

the future. With rent payments being delayed, our landlords may, at their option, (a) terminate our headquarters and manufacturing leases or could take other actions that restrict our ability to operate the business or (b) keep the lease in place and continue to have the right to collect rent as and when it becomes due for the remainder of the term of such lease.

Certification of a new manufacturing facility can be time consuming and expensive and requires personnel resources that we may not have or access to. We may be unsuccessful in our efforts to move manufacturing, which could negatively impact our ability to manufacture product in the future.

We have dramatically reduced our senior management team and cannot assure you that we have sufficient resources to accomplish our business plan.

Our success largely depends upon the services of our executive management team, which was recently reduced to Andy Rasdal, our President and CEO, and Nooshin Hussainy, our Chief Financial Officer. Our former President and CEO, William Plovanic resigned on June 19, 2020. Mr. Plovanic continues to serve as a member of the Board of Directors. Mark Brister, our Chief Technology Officer, and Amy VandenBerg, our Chief Clinical, Regulatory and Quality Officer, resigned on July 3, 2020 but continue to provide limited services on a consulting basis. Bob MacDonald, our Chief Retail Officer, resigned on March 13, 2020. We cannot assure you that the remaining executives will be sufficient to implement our current business plan. Additionally, we do not currently maintain key personnel life insurance policies on any of our employees. Moreover, if we are successful in securing reimbursement for our products, we will need to attract and retain additional executive officers and numerous highly qualified personnel. Competition for executive officers and skilled personnel is intense. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. If we are unable to attract and retain additional executive officers or other key employees it could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

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, are particularly focused on the value of the stock awards they receive in connection with their employment. As a result, the current market price of our common stock, in particular as it relates to exercise prices of our outstanding options, limits our ability to retain existing employees and makes it difficult to attract additional 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.

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.

In the future, our Obalon Balloon System may be subject to product recalls that could harm our reputation and business.

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

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

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

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

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

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

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

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

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

- impairment of our brand and business reputation;
- costly litigation;

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

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

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

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

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

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

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

Since February 2017, the FDA has issued four separate letters (known as Safety Alerts) to health care providers warning of serious adverse events, including deaths, which are specific to liquid-filled intragastric balloons. While the Safety Alerts were specific to liquid-filled intragastric balloons and not gas-filled intragastric balloons, these adverse events could result in the FDA taking action against the entire intragastric balloon category which may cause negative consequences for us including

requiring additional warnings, precautions and/or contraindications in the labeling than originally required, delaying or denying approval of our future products, or possible review or withdrawal of our current approval.

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

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

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

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

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

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory, product development tasks, quality assurance, clinical data, and customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or other catastrophic events. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Numerous and evolving cybersecurity threats pose potential risks to the security of our information technology systems, networks and products, as well as the confidentiality and integrity of our data. A security breach could impact the use of such products and the security of information stored therein.

The failure of our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory efforts and significantly increase our costs to recover or reproduce the data. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify
individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors or contractors. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue, regulatory actions or litigations. To the extent that any disruption or security breach were to result in a loss of or damage to our

data or applications, or inappropriate disclosure of confidential or proprietary information, we could also incur liability. Any of these events could have a material adverse effect on our reputation, business, financial condition and results of operations.

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

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

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

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

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

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

In our Company-managed Obalon-branded retail treatment centers payment is collected from the patient in advance of initiation of treatment and payments will be handled the same way for any future Company-owned or managed Obalon-branded treatment centers. Third party financing is offered at the Obalon Center for Weight Loss™ by companies that specialize in that service. If patients are not satisfied with the outcome of the treatment, or experience complications or early removals, they may request refunds. We reserve for sales returns as a reduction of revenue. If we experience a higher than expected request for refunds, it could have a negative impact on our revenue or results of operations.

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

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

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

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

We hold a number of insurance policies, including directors' and officers' liability insurance, product liability insurance, business interruption insurance, medical malpractice, property insurance and workers' compensation insurance. The cost of maintaining directors’ and officers’ liability insurance and product liability insurance on implantable medical devices has

increased substantially over the past few years and could continue to increase, due to general market trends, as part of an evaluation of our specific loss history and other factors. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become economically impractical or become unavailable to us due to exhaustion of the coverage or any other reason, we would be required to operate our business without indemnity from commercial insurance providers.

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

At December 31, 2019, we had federal and state net operating loss carryforwards, or NOLs, of approximately $147.9 million and $114.6 million, respectively. The federal and state tax loss carryforwards will begin expiring in 2028, unless previously utilized. The federal net operating loss carryover includes $59.7 million of net operating losses generated after 2017. Federal net operating losses generated in 2018 and beyond carryover indefinitely and may be generally be used to offset up to 80% of future taxable income. We also had federal and California research and development tax credit carryforwards totaling $3.4 million and $2.7 million respectively. The federal research and development tax credit carryforward will begin to expire in 2028 unless previously utilized. The California research tax credits do not expire.

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

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

RISKS RELATED TO REGULATORY MATTERS

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

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

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

In addition, as a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. For example, as part of our PMA approval, we are required to conduct a post-approval study at up to 16 sites in the United States to evaluate the safety and efficacy of our Obalon Balloon System in approximately 200 subjects over a twelve-month period, consisting of six months of treatment with the Obalon Balloon System followed by six months of observation after balloon removal. We began patient enrollment in the post approval study in the second quarter of 2018 and in April 2019 we notified the FDA that we had temporarily paused active new patient enrollment to conserve cash resources and ensure we could meet future financial obligations to physicians and patients. We have subsequently notified the FDA in July 2019 that we restarted enrollment and as of March 31, 2020 we enrolled approximately 200 patients, which we believe represents full enrollment. As part of our PMA-S approval of the Obalon Navigation System, we are required to conduct a post-approval study at up to 40 sites in the United States to evaluate the safety

and efficacy of our Obalon Navigation System for approximately 4,000 balloon placements, as it relates to the safety and efficacy of acute balloon placement including deployment, but not long-term results such as weight loss. We began enrollment of the Obalon Navigation System post-approval study in December 2019. In the first quarter of 2020, we enrolled 32 patients with 81 balloon administrations in the Obalon Navigation System post-approval study. We have notified the FDA that we have temporarily paused active new patient enrollment as a result of ceasing to ship new product to commercial customers and the closure of the Obalon-branded retail treatment centers. We intend to keep this study paused until we secure a pathway to a product reimbursement trial where we will evaluate how to collect the data required to support this study in conjunction with the data required of a third-party payor. The product labeling for any product subject to a post-approval study must be updated and submitted in a PMA supplement as results, including any adverse event data, from the post-approval study data become available. Failure to conduct post-approval studies in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would materially harm our business. Moreover, if post-approval studies of our products reveal unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures, and we are required to modify the approved labeling for our products to include such adverse findings, such labeling modifications could have a materially adverse effect on our ability to market and sell the affected products.

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

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

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

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

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

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

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

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

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

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

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

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

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA numerous times, the most recent of which occurred in November 2017, which resulted in no observations. Although we believe our manufacturing facilities and those of our critical component suppliers are in compliance with the QSR requirements, we can provide no assurance that we will continue to remain in compliance with the QSR. If our manufacturing facilities or those of any of our component suppliers are found to be in violation of applicable laws and

regulations, or we or our suppliers have significant noncompliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

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

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

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

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

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

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

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

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

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

Further, the FDA and European regulatory authorities strictly regulate the indications for use and associated promotional safety and effectiveness claims, including comparative and superiority claims vis a vis competitors' products, that may be made about products, such as the Obalon Balloon System. In particular, a medical device may not be promoted for uses or indications that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. For example, we will not be able to promote or make claims for the Obalon Balloon System for the treatment of patients outside of the BMI ranges specifically approved by the FDA or other regulatory authorities. In the United States, we received FDA approval of the Obalon Balloon System for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40) who have failed to lose weight through diet and exercise. The Obalon Balloon System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed. Our pivotal trial inclusion and exclusion criteria included patients with a BMI of 30 to 40; thus, our approved labeling is limited to the same BMI range. We also will not be able to make comparative or superiority claims for the Obalon Balloon System versus other products without scientific data supporting or establishing those claims, including possibly data from head-to-head clinical trials if appropriate. Our CE mark label includes patients with a BMI of 27 or greater. As a part of our PMA approval, we are required to conduct a post-approval study at up to 16 sites in the United States to evaluate the safety and efficacy of our Obalon Balloon System over a twelve-month period, consisting of six months of treatment with the Obalon Balloon System followed by six months of observation after balloon removal. We began patient enrollment in the post-approval study in the second quarter of 2018 and in April 2019 we notified the FDA that we had temporarily paused active new patient enrollment to conserve cash resources and ensure we could meet future financial obligations to physicians and patients. We have subsequently notified the FDA in July 2019 that we restarted enrollment and as of December 31, 2019 we enrolled 187 patients. Failure to conduct post-approval studies in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would materially harm our business. As part of our PMA-S approval of the Obalon Navigation System, we are required to conduct a post-approval study of up to 40 sites in the United States to evaluate the safety and efficacy of our Obalon Navigation System as it relates to acute balloon placement including deployment. We began enrollment of the Obalon Navigation System post approval study in December 2019. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies, obtaining results different than our pivotal trial results or failure to comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

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

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, and regulatory authorities outside the United States may adopt similar

restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

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

- ***Other Healthcare Fraud Laws.*** HIPAA includes criminal health care fraud provisions and related rules that prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing or covering up a material fact or making any material false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- ***Transparency Laws.*** There has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals and entities. For example, the Physician Payment Sunshine Act, imposes annual reporting requirements on certain manufacturers of drugs, medical devices, biologics and medical supplies with respect to payments and other transfers of value provided by them, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as with respect to certain ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information regarding all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on medical device manufacturers' marketing practices, require reporting of marketing and pricing information, and require the tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities under certain circumstances.

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

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

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

The practice of medicine is highly regulated, and our operation of retail treatment centers, arrangements with physicians and interactions with retail customers in the near future will be subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Regulatory oversight includes, but is not limited to, the corporate practice of medicine, fee-splitting, regulation and registration of medical practices, clinics and facilities and management companies by state and

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

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

Federal, state, and local laws and policies impose various registration, accreditation, permit and/or licensing requirements on healthcare facilities and subject healthcare facilities to regulations ranging from the adequacy of medical care, to compliance with building codes and environmental protection laws. Additionally, physicians at our retail treatment centers, once operational, will also be subject to various state and federal regulations, including utilization of diagnostic tests and regarding prescribing medication and controlled substances. Delays or failures to obtain or maintain any required registrations, accreditations, permits and other licenses could adversely impact our ability to establish and operate our retail treatment centers.

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

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

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

HIPAA requires 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 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 business associates to safeguard the covered entity's PHI against improper use and disclosure. In addition, a business associate may face significant statutory and contractual liability if the business associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. We believe that our Company-owned or managed treatment centers are required to be HIPAA compliant; we do not believe our corporate offices are required to be HIPAA compliant, but are nevertheless committed to maintaining the security and privacy of patients' health information. Violation of HIPAA could result in the imposition of civil or criminal penalties.

Numerous other federal, state and foreign laws may apply that restrict the use and protect the privacy and security of PII, including health information. These include state medical privacy laws, state social security number protection laws, state breach notification laws, and federal and state consumer protection laws. These various laws in many cases are not preempted by HIPAA and may be subject to varying interpretations by the courts and government agencies. For instance, In Europe, the GDPR, went into effect in May 2018 and imposes stringent data protection requirements for controllers and processors of personal data of persons within the EU. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

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

Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. We expect that there will continue to be new proposed laws, regulations and industry standards concerning privacy, data protection and information security in the United States, including the California Consumer Privacy Act, which went into effect January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. We cannot yet determine the impact such future laws, regulations and standards may have on our business. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, including health data, along with increased patient demands for enhanced data security infrastructure, could greatly increase our cost of providing our services, decrease demand for our services, reduce our revenue and/or subject us to additional liabilities.

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

As of June 30, 2020, we held 29 issued U.S. patents and had 17 pending U.S. patent applications, as well as 22 international patents issued in regions including Europe, Mexico, Australia, Canada, Asia, and China and 59 pending international patent applications in regions including Australia, Canada, Europe, Asia, the Middle East and South America. Our issued patents expire between the years 2023 and 2038, and are directed to various features and combinations of features of the Obalon Balloon System technology, including the apparatus for connecting the balloon to an inflation catheter, the structure and composition of the balloon wall, and the composition of the initial fill gas.

As of June 30, 2020, we held two registered U.S. trademarks and 34 registered marks in Europe, the Middle East, Asia and Mexico. We have four pending U.S. trademark applications and no pending marks outside the United States.

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

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

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect the Obalon Balloon System or any other products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our Obalon Balloon System before our relevant patents expire;
- we were the first to make the inventions shown in each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable;
- our commercial activities or products will not infringe the patents of others; or
- we will be in the financial position to defend our trademarks and patents.

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

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

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

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

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

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

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

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

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

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

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

recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

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

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

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

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

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

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

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

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

If we initiated legal proceedings against a third party to enforce one of our patents, the defendant could counterclaim that the patent is invalid and/or unenforceable. Even if legal proceedings were not initiated, if we threatened a third party with a patent infringement lawsuit, the third party preemptively may sue us in a declaratory judgment action and seek to have our patent declared invalid or not infringed. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our products or competitive products. The outcome

following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse impact on our business. An adverse result in any legal proceeding could put one or more of our patents at risk of being invalidated, found unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

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

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

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

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

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

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

Many of our current and former 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 current and former 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 a current or former 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

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On February 5, 2020, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15,000,000 of our common stock. The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement filed with the SEC on February 7, 2020. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park under the Purchase Agreement. Sales of our common stock, if any, to Lincoln Park under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

As of June 30, 2020 we have not sold any shares of our stock under the Purchase Agreement with Lincoln Park.

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 can be affected by a number of factors, including:

- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- whether we obtain coverage and reimbursement from third-party payors;
- quarterly variations in our or our competitors' results of operations;
- the results of our clinical trials;
- unanticipated or serious safety concerns related to the use of any of our products or competitive liquid-filled intragastric balloon products;
- adverse regulatory decisions, including failure to receive regulatory approval for any of our products;
- regulatory or legal developments in the United States and other countries;
- changes in analysts’ estimates, investors’ perceptions, recommendations by securities analysts or our failure to achieve analysts’ estimates;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- performance of third parties on whom we rely, including for the manufacture of the components for our product, including their ability to comply with regulatory requirements;
- inability to obtain adequate supply of the components for any of our products, or inability to do so at acceptable prices;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation of our business;

- changes in the structure of healthcare payment systems;
- our commencement of, or involvement in, litigation;
- the announcement of new products or product enhancements by us or our competitors;
- competition from existing technologies and products or new technologies and products that may emerge;
- negative publicity, such as whistleblower complaints, about us or our products;
- developments, announcements or disputes related to patents or other proprietary rights issued to us or our competitors and to litigation;
- ability to meet Nasdaq minimum listing requirements; and
- developments in our industry.

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

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

Nasdaq monitors our ongoing compliance with its minimum listing requirements and if we fail to meet those requirements and cannot cure such failure in the prescribed period of time, our common stock could be subject to delisting from the Nasdaq market. As of June 30, 2020, our shareholder equity has decreased below the $10,000,000 minimum. If the deficiency occurs for a period of 30 consecutive business days, we could receive written notification from Nasdaq for non-compliance.

Since the COVID-19 pandemic began, the closing bid for our common stock has consistently been below $1.00. Our common stock has closed below $1.00 every day since June 19, 2020. If our closing bid price remains under $1.00 for 30 consecutive business days, we will receive a notice of noncompliance from Nasdaq. We cannot assure you that the closing price of our common stock will be at or above $1.00 per share for a sufficient period to enable us to avoid notification of non-compliance with this listing requirement.

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

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

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

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

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, including pursuant to the Purchase Agreement with Lincoln Park. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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.

Our management will have broad discretion over the use of the net proceeds from our sale of shares of common stock to Lincoln Park, you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from our sale of shares of common stock to Lincoln Park, and we could use them for purposes other than those contemplated at the time of commencement of the offering. Accordingly, you will be relying on the judgment of our management with regard to the use of those net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest those net proceeds in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flows.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

As a public company, and particularly after we are no longer an emerging growth company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act

of 2002 and rules subsequently implemented by the SEC and Nasdaq, have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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

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

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

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

As of June 30, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 21% of our outstanding capital stock. These stockholders may be able to influence the outcome of matters requiring stockholder approval. For example, these stockholders may be able to influence elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are subject to securities class action litigation.

On February 14 and 22, 2018, plaintiff stockholders filed class action lawsuits against us and certain of our executive officers in the United States District Court for the Southern District of California (Hustig v. Obalon Therapeutics, Inc., et al., Case No. 3:18-cv-00352-AJB-WVG, and Cook v. Obalon Therapeutics, Inc. et al., Case No. 3:18-cv-00407-CAB-RBB). On July 24, 2018, the court consolidated the lawsuits and appointed Inter-Local Pension Fund GCC/IBT as lead plaintiff. On October 5, 2018, plaintiffs filed an amended complaint. The amended complaint alleges that we and certain of our executive officers made false and misleading statements and failed to disclose material adverse facts about our business, operations, and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The amended complaint also alleges violations of Section 11 of the Exchange Act arising out of

the Company's initial public offering. The plaintiffs seek damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The underwriters from our initial public offering have also been named as defendants in this case and we have certain obligations under the underwriting agreement to indemnify them for their costs and expenses incurred in connection with this litigation.

On September 25, 2019, the court granted in part and denied in part the defendants' motion to dismiss. The court dismissed the Section 11 claims entirely, without leave to amend, and accordingly dismissed the underwriters and certain directors from the case. The Court also dismissed certain statements from the Section 10 claims.

On June 16, 2020, the parties reached a settlement of the securities class action, and they intend to submit a final settlement agreement for court approval. The settlement provides for a payment of $3.15 million to the plaintiffs, and provides that the defendants continue to deny the allegations and claims asserted by the plaintiffs, and are entering into the settlement solely to eliminate the burden and expense of further litigation. The Company expects that any amounts due as part of the settlement will be covered by the Company's insurance policies.

On December 12, 2019, a purported stockholder submitted a formal demand letter to the Board asserting similar alleged wrongdoing as alleged in the securities class action and demanding that the Board investigate the alleged wrongdoing and take action to remedy the alleged injury to the Company. The Board's review of the demand is on-going.

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

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

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

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

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

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

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

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

We have never declared or paid any cash dividends on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Any return to stockholders will be limited to the appreciation of stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in the value of the stock. We cannot guarantee you that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

None.

ITEM 3. Defaults Upon Senior Securities

Not applicable.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

Exhibit Number	Description of Document	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1/A filed on September 26, 2016).	
3.2	Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 14, 2018).	
3.3	Certificate of Second Amendment to the Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 24, 2019).	
3.4	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1/A filed on September 26, 2016).	
10.1	Promissory Note, dated as of April 22, 2020, by and between Obalon Therapeutics, Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 27, 2020).	
10.2‡	Form of Stock Option Agreement (Cash Settlement)	X
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 of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101.INS	XBRL Instance Document.	X
101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X

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

‡ Management contract or compensatory plan or arrangement.

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: July 30, 2020

by: /s/ Andrew Rasdal

Andrew Rasdal

President & Chief Executive Officer

NOTICE OF STOCK OPTION GRANT

(WITH CASH SETTLEMENT)

OBALON THERAPEUTICS INC. 2016 EQUITY INCENTIVE PLAN

Unless otherwise defined herein, the terms defined in the Obalon Therapeutics Inc. (the "***Company***") 2016 Equity Incentive Plan (the "***Plan***") shall have the same meanings in this Notice of Stock Option Grant (the "***Notice of Grant***") and the attached Stock Option Agreement, including any special terms and conditions for your country set forth in the appendix attached thereto (collectively, the "***Option Agreement***"). You have been granted an option to receive a cash payment as set forth below (the "***Option***"), subject to the terms and conditions of the Plan, this Notice of Grant and the Option Agreement.

Name:	
Date of Grant:	
Exercise Price per Share:	
Total Number of Shares:	52,865
Type of Option:	Non-Qualified Stock Option
Expiration Date:	[_____]; this Option expires earlier if your Service terminates earlier, as described in the Option Agreement.
Vesting Schedule:	This Option shall vest as to 1/36th of the Shares underlying the Option on each monthly anniversary of the Date of Grant, subject to your continued service with the Company through the applicable vesting date.

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

GRANTEE

By:
Print Name:

OBALON THERAPEUTICS INC.

By:
Raymond Dittamore
Director

STOCK OPTION AGREEMENT

(WITH CASH SETTLEMENT)

OBALON THERAPEUTICS INC. 2016

EQUITY INCENTIVE PLAN

You have been granted an Option by Obalon Therapeutics Inc. (the "***Company***") under the 2016 Equity Incentive Plan, as amended from time to time (as amended, the "***Plan***") for that number of Shares (the "***Option***") set forth in the Notice of Stock Option Grant (the "***Notice of Grant***") representing the right to a cash payment (the "***Option Payment***") equal to the excess, if any, of (i) the Fair Market Value of each such Share on the date of exercise over (ii) the exercise price per Share set forth in the Notice of Grant (the "***Exercise Price***"). This Option may not be exercised for Shares of the Company's Common Stock. The Option is subject to the terms, restrictions and conditions of the Plan, the Notice of Grant and this Stock Option Agreement, including any special terms and conditions for your country set forth in the appendix attached hereto (the "***Appendix***") (collectively, the "***Agreement***").

1. **Grant of Option**. You have been granted the Option for the number of Shares set forth in the Notice of Grant representing the right to receive the Option Payment. In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of this Agreement, the terms and conditions of the Plan shall prevail.

2. **Termination**.

(a) General Rule. If your Service terminates for any reason except death or Disability, and other than for Cause, then this Option will expire at the close of business at Company headquarters on the date three months after your termination of Service (subject to the expiration detailed in Section 5). If your Service is terminated for Cause, this Option will expire upon the date of such termination.

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

(b) Death; Disability. If you die before your Service terminates (or you die within three months of your termination of Service other than for Cause), then this Option will expire at the close of business at Company headquarters on the date 12 months after the date of death (subject to the expiration detailed in Section 5). If your Service terminates because of your Disability, then this Option will expire at the close of business at Company headquarters on the date 12 months after your termination date (subject to the expiration detailed in Section 5).

(c) Termination Date. For purposes of this Option, your Service will be considered terminated as of the date you are no longer actively providing services to the Company or a Parent, Subsidiary or Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are employed or engaged or the terms of your employment or consulting agreement, if any), and your period of Service will not include any contractual notice period or any period of "garden leave" or similar period mandated under labor laws in the jurisdiction where you are employed or engaged or the terms of your

employment or consulting agreement, if any. The Committee shall have the exclusive discretion to determine when you are no longer actively providing services for purposes of this Option (including whether you may still be considered to be providing services while on a leave of absence).

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

3. **Exercise of Option**.

(a) Right to Exercise. Any portion of the Option that vests in accordance with the vesting schedule set forth in the Notice of Grant and the applicable provisions of the Plan and this Agreement will become exercisable as follows:

1. To the extent the Option vests prior to or on December 31, 2020, the Option will become exercisable on the earliest to occur of (i) January 1, 2021, (ii) your death or Disability and (iii) the consummation of a Corporate Transaction and pursuant to the terms of the agreement evidencing such Corporate Transaction.

2. To the extent the Option vests following January 1, 2021, the Option will become exercisable as of the applicable vesting date.

3. In the event of your death, Disability, or other cessation of Service, the exercisability of the Option is governed by the applicable provisions of the Plan, the Notice of Grant and this Agreement.

(b) Method of Exercise. This Option is exercisable by delivery of an exercise notice in a form specified by the Company (the "***Exercise Notice***"), which shall state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the "***Exercised Shares***"), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice shall be delivered in person, by mail, via electronic mail or facsimile or by other authorized method to the Secretary of the Company or other person designated by the Company. The Exercise Notice shall be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares; the payment of the aggregate Exercise Price shall be by personal check, wire transfer, or a cashier's check, or an amount in cash sufficient to satisfy such aggregate Exercise Price may be withheld from the Option Payment. This Option shall be deemed to be exercised upon receipt by the Company of a fully executed Exercise Notice accompanied by the aggregate Exercise Price and any applicable withholding of Tax-Related Items as detailed in Section 7 below. No Option Payment shall be made pursuant to the exercise of an Option unless such issuance and such exercise comply with all relevant provisions of law. Assuming such compliance, for income tax purposes the Option Payment shall be considered paid to you on the date on which the Option is exercised.

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

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

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

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

5. **Term of Option**. This Option shall in any event expire on the expiration date set forth in the Notice of Grant, which date is ten years after the grant date.

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

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

7. Responsibility for Taxes. Regardless of any action the Company or, if different, your actual employer (the "***Employer***") takes with respect to any or all income tax, social insurance contributions, payroll tax, fringe benefits tax, payment on account or other tax-related withholding ("***Tax- Related Items***"), you acknowledge that the ultimate liability for all Tax-Related Items legally due by you is and remains your responsibility and that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of this Option, including the grant, vesting or exercise of this Option and the subsequent payment by the Company of the Option Payment pursuant to such exercise; and (2) do not commit to structure the terms of the grant or any aspect of this Option to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You acknowledge that if you are subject to Tax-Related Items in more than one jurisdiction, the Company and/or the Employer may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to exercise of the Option, you shall pay or make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Item withholding and payment on account obligations of the Company and/or the Employer. In this regard, you authorize the Company and/or the

Employer, and their respective agents, at their discretion, to withhold all applicable Tax-Related Items legally payable by you from the Option Payment in an amount of cash sufficient to satisfy the applicable tax withholding obligation.

Finally, you agree to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold as a result of your participation in the Plan or your receipt of the Option Payment that cannot be satisfied by the means previously described. You acknowledge that the Company has no obligation to deliver the Option Payment to you until you have satisfied the obligations in connection with the Tax-Related Items as described in this Section.

8. Nature of Grant. In accepting this Option, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

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

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

(d) you are voluntarily participating in the Plan;

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

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

(g) unless otherwise agreed with the Company, this Option and the Option Payment, and the income and value of same, are not granted as consideration for, or in connection with, any Service you may provide as a director of any Parent, Subsidiary or Affiliate;

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

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

(j) no claim or entitlement to compensation or damages shall arise from forfeiture of this Option resulting from the termination of your Service (for any reason whatsoever, whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are employed or engaged or the terms of your employment or service agreement, if any), and in consideration of the grant of this Option to which you are otherwise not entitled, you irrevocably agree never to institute any claim against the Company, the Employer or any Parent, Subsidiary or Affiliate, waive your ability, if any, to bring any such claim, and

release the Company, the Employer or any Parent, Subsidiary or Affiliate from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, you shall be deemed irrevocably to have agreed not to pursue such claim and agree to execute any and all documents necessary to request dismissal or withdrawal of such claim; and

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

9. **Data Privacy**. You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Agreement and any other Option grant materials by and among, as applicable, the Employer, the Company and any Parent, Subsidiary or Affiliate for the exclusive purpose of implementing, administering and managing your participation in the Plan.

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares or directorships held in the Company, details of all stock options or any other entitlement to shares awarded, canceled, exercised, vested, unvested or outstanding in your favor ("**Data**"), for the exclusive purpose of implementing, administering and managing the Plan.

You understand that Data will be transferred to third parties in connection with the implementation, administration and management of the Plan. You understand that the recipients of Data may be located in the United States or elsewhere, and that the recipient's country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that if you reside outside the United States, he or she may request a list with the names and addresses of any potential recipients of Data by contacting your local human resources representative. You authorize the Company and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer

Data, in electronic or other form, for the sole purposes of implementing, administering and managing your participation in the Plan. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understands that if you reside outside the United States, you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. Further, you understand that you are providing the consents herein on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your Service status and career with the Employer will not be adversely affected; the only consequence of refusing or withdrawing your consent is that Company would not be able to grant you stock options or other equity awards or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

10. **Acknowledgement**. The Company and you agree that this Option is granted under and governed by the Notice of Grant, this Agreement and the provisions of the Plan (incorporated herein by reference). You: (i) acknowledge receipt of a copy of the Plan prospectus, (ii) represent that

you have carefully read and are familiar with the provisions in the grant documents, and (iii) hereby accept this Option subject to all of the terms and conditions set forth in this Agreement and those set forth in the Plan and the Notice of Grant. You hereby agree to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice of Grant and this Agreement.

11. **Consent to Electronic Delivery and Acceptance of All Plan Documents and Disclosures**. By your acceptance of this Option, you consent to the electronic delivery of the Notice of Grant, this Agreement, account statements, Plan prospectuses required by the SEC, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its stockholders (including, without limitation, annual reports and proxy statements) or other communications or information related to this Option. Electronic delivery may include the delivery of a link to a Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. You acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost if you contact the Company by telephone, through a postal service or electronic mail at [insert email]. You further acknowledge that you will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, you understand that you must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. You agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company. Also, you understand that your consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if you have provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail at [insert email]. Finally, you understand that you are not required to consent to electronic delivery.

12. **Compliance with Laws and Regulations**. The exercise of this Option will be subject to and conditioned upon compliance by the Company and you with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Common Stock may be listed or quoted at the time of such issuance or transfer, which compliance the Company shall, in its absolute discretion, deem necessary or advisable. You understand that the Company is under no obligation to register or qualify the Common Stock with any state, federal or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the Shares. Further, you agree that the Company shall have unilateral authority to amend the Plan and this Agreement without your consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares.

13. **No Advice Regarding Grant**. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or the Option Payment, if any. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

14. **Governing Law; Venue**. This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law. For purposes of litigating any dispute that may arise directly or indirectly from the Plan, the Notice of Grant and this Agreement, the parties hereby submit and consent to litigation in the exclusive jurisdiction of the State of California and agree that any such litigation shall be conducted only in

the courts of California in San Diego County, California or the federal courts of the United States for the Southern District of California and no other courts.

15. **Severability**. If one or more provisions of this Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this Agreement, (ii) the balance of this Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of this Agreement shall be enforceable in accordance with its terms.

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

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

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

19. **Entire Agreement; Enforcement of Rights.** This Agreement, the Plan and the Notice of Grant constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning this Option are superseded. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, shall be effective unless in writing and signed by the parties to this Agreement; provided, however, that the Company may in its sole discretion and without your consent amend this Agreement to provide for the stock settlement of the Option and/or to provide that substantially the same terms and conditions (other than vesting schedules) that apply to the Company's stock-settled stock option awards shall apply to the Option. The failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of any rights of such party.

20. **Insider Trading Restrictions/Market Abuse Laws**. You acknowledge that you may be subject to insider trading restrictions and/or market abuse laws, which may affect your ability to receive the Option Payment during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you are advised to speak to your personal advisor on this matter.

21. **Language**. If you have received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

22. **Appendix**. Notwithstanding any provisions in this Agreement, this Option shall be subject to any special terms and conditions set forth in any Appendix hereto for your country. Moreover, if you relocate to one of the countries included in the Appendix, the special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

23. **Imposition of Other Requirements**. The Company reserves the right to impose other requirements on your participation in the Plan, on this Option and on the Option Payment, if any, to

the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

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

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

Exhibit 31.1

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

I, Andrew Rasdal, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: July 30, 2020

/s/ Andrew Rasdal

Andrew Rasdal

President and Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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

I, Nooshin Hussainy, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: July 30, 2020

/s/ Nooshin Hussainy

Nooshin Hussainy
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO SECTION 906

OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Obalon Therapeutics, Inc. (the "Company") for the quarter ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Andrew Rasdal, the President and Chief Executive Officer, and Nooshin Hussainy, the Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his and her knowledge:

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

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

Dated: July 30, 2020

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

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