

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 19, 2020

OBALON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001- 37897

(Commission
File Number)

26-1828101

(IRS Employer
Identification No.)

**5421 Avenida Encinas, Suite F
Carlsbad, California**

(Address of principal executive offices)

92008

(Zip Code)

(844) 362-2566

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company S

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 financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. S

Item 2.02. Results of Operations and Financial Condition.

On June 19, 2020 Obalon Therapeutics, Inc. (the “Company”) reported its financial results for the three months ended March 31, 2020. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information furnished with Item 2.02 of this report, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated June 19, 2020

SIGNATURE

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: June 19, 2020

By:

/s/ William Plovanic

William Plovanic

President and Chief Executive Officer

Obalon Announces First Quarter 2020 Financial Results and Business Update

SAN DIEGO, CA June 19, 2020 (GLOBE NEWSWIRE) -- Obalon Therapeutics, Inc. (Nasdaq: OBLN), a weight loss solutions company with the first and only FDA-approved swallowable, gas-filled intragastric balloon system for the treatment of obesity, today announced its financial results for the first quarter ended March 31, 2020 and provided a business update.

Financial results for the first quarter of 2020

Revenue for the first quarter of 2020 was \$0.8 million, compared to \$1.8 million for the first quarter of 2019. Net loss for the first quarter of 2020 was \$5.3 million, compared to \$8.3 million for the first quarter of 2019. Net loss per share for the first quarter of 2020 was \$0.68, compared to \$3.59 for the first quarter of 2019.

Cost of revenue was \$0.5 million for the first quarter of 2020, down from \$1.2 million for the first quarter of 2019.

Gross profit for the first quarter of 2020 was \$0.2 million, down from \$0.5 million for the first quarter of 2019.

Research and development expense for the first quarter of 2020 totaled \$1.3 million, down from \$2.4 million for the first quarter of 2019. Selling, general and administrative expense decreased to \$3.9 million for the first quarter of 2020, compared to \$6.2 million for the first quarter of 2019.

Operating loss for the first quarter of 2020 was \$4.9 million, down from a loss of \$8.1 million for the first quarter of 2020.

In the first quarter ended March 31, 2020, the Company did not record any asset impairment charges, but it would expect to record certain long-lived asset and inventory impairment charges in the second quarter ended June 30, 2020 related to its decision to move away from the retail treatment center model. The Company estimates the second quarter impairment charge to be in a range between \$0.8 million and \$1.4 million.

As of March 31, 2020, the Company had cash and cash equivalents of \$8.9 million and no debt. The Company believes its cash and cash equivalents as of March 31, 2020 are sufficient to fund its operations only through the end of 2020. If the Company is not able to raise additional capital to meet its needs, it will not be able to support any ongoing operations and may not be able to settle all of its liabilities. The Company has 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 its capital needs and financial obligations, and to date it has been unable to identify a viable alternative for capital raising.

Business update

On June 16, 2020, the Company and certain of its executive officers reached a settlement with the plaintiffs in its ongoing securities class action litigation, and they intend to submit a final settlement agreement for court approval. The settlement 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.

In March 2020, the Company 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 its business. As a result, the Company halted sales to new patients in its company-branded retail treatment centers, terminated expansion plans for

additional retail centers and subsequently closed the two retail treatment centers it had opened. The Company also halted manufacturing operations and has not filled orders to U.S. customers or its former international distributor since that time.

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, the Company does not currently plan to re-open its retail treatment centers, re-initiate its retail treatment center expansion plans, or plan to ship orders to U.S. customers or its former international distributor. As a result, the Company would not expect to report any meaningful revenue for the foreseeable future.

The Company continues 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. The Company believes 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 procedure. With that in mind, the Company is initiating efforts to explore obtaining third-party payor reimbursement and coverage for the Obalon Balloon System. The Company believes that reimbursement and coverage for the Obalon Balloon System could significantly expand its 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. The Company believes the Obalon Balloon System could help reduce third-party payors' costs and improve patient care,

and the Company intends 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 the Company's success. If the Company's initial efforts with payors begin to bear success, it would expect to need to raise additional capital to support those efforts.

To enable it to pursue this reimbursement strategy, the Company is taking further steps to significantly reduce expenses in an effort to extend its cash runway. The Company has significantly reduced the organization to only essential personnel and expects that, after a transition, only two full-time employees will remain: Andy Rasdal, the current Executive Chairman of the Board, who effective as of the close of business on the date of this quarterly report will reassume the role of CEO, and Nooshin Hussainy, who will remain Chief Financial Officer. During this time the Company also plans to continue to seek strategic alternatives that may be in the best interests of its stockholders, while it explores establishing third party coverage and reimbursement for the Obalon Balloon System. If the Company is unsuccessful in either of these two endeavors over the next several months, there is a high likelihood it may need to sell all or portions of its business, liquidate all or some of its assets or seek bankruptcy protection, any of which could result in a significant decrease in value for all stakeholders. If the Company determines to proceed with a plan to establish reimbursement coverage for its products, it will need additional capital to fund operations beyond the end of 2020 and there is no assurance that such capital will be available on acceptable terms or at all.

About Obalon Therapeutics, Inc.

Obalon Therapeutics, Inc. (Nasdaq: OBLN) is a San Diego-based company focused on developing and commercializing novel technologies for weight loss. For more information, please visit <http://www.obalon.com>.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that are not purely historical regarding Obalon's or its management's intentions, beliefs, expectations and strategies for the future, including those related to new products and their potential benefits. All forward-looking statements and reasons why results might differ included in this press release are made as of the date of this release, based on information currently available to Obalon, deal with future events, are subject to various risks and uncertainties, and actual results could differ materially from those anticipated in those forward looking statements. The risks and uncertainties that may cause actual results to differ materially from Obalon's current expectations are more fully described in Obalon's annual report on Form 10-K for the period ended December 31, 2019, periodic report on Form 10-Q for the period ended March 31, 2020 and its other reports, each as filed with the Securities and Exchange Commission. Except as required by law, Obalon assumes no obligation to update any such forward-looking statement after the date of this report or to conform these forward-looking statements to actual results.

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Revenue	\$ 780	\$ 1,775
Cost of revenue	541	1,232
Gross profit	239	543
Operating expenses:		
Research and development	1,257	2,439
Selling, general and administrative	3,893	6,204
Total operating expenses	5,150	8,643
Loss from operations	(4,911)	(8,100)
Interest income (expense), net	35	(190)
Other expense, net	(385)	—
Net loss and comprehensive loss	\$ (5,261)	\$ (8,290)
Net loss per share, basic and diluted	\$ (0.68)	\$ (3.59)
Weighted-average common shares outstanding, basic and diluted	7,725,205	2,311,329

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

	March 31, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,915	\$ 14,055
Accounts receivable, net	461	285
Inventory	1,408	1,936
Other current assets	4,786	1,959
Total current assets	15,570	18,235
Property and equipment, net	2,159	1,081
Lease right-of-use assets	1,500	1,077
Total assets	\$ 19,229	\$ 20,393
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,070	\$ 648
Accrued compensation	359	820
Deferred revenue	462	424
Other current liabilities	4,607	1,524
Current portion of lease liabilities	690	561
Total current liabilities	7,188	3,977
Lease liabilities long-term	969	567
Total liabilities	8,157	4,544
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 7,731,633 and 7,724,100 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	8	8
Additional paid-in capital	188,755	188,271
Accumulated deficit	(177,691)	(172,430)
Total stockholders' equity	11,072	15,849
Total liabilities and stockholders' equity	\$ 19,229	\$ 20,393

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Operating activities:		
Net loss	\$ (5,261)	\$ (8,290)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	103	150
Stock-based compensation	470	1,105
Amortization of right-of-use asset	122	92
Accretion of investment discount, net	—	(2)
Amortization of debt discount	—	22
Change in operating assets and liabilities:		
Accounts receivable, net	(176)	(959)
Inventory	(326)	102
Other current assets	(2,828)	923
Accounts payable	422	(137)
Accrued compensation	(446)	(2,819)
Deferred revenue	38	18
Lease liabilities, net	(14)	(42)
Other current liabilities	3,082	195
Net cash used in operating activities	(4,814)	(9,642)
Investing activities:		
Maturities of short-term investments	—	2,550
Purchases of property and equipment	(326)	(19)
Net cash (used in) provided by investing activities	(326)	2,531
Financing activities:		
Proceeds from long-term loan	—	10,000
Proceeds from issuance of common stock, net of issuance costs	—	607
Proceeds from sale of common stock upon exercise of stock options	—	1
Net cash provided by financing activities	—	10,608
Net (decrease) increase in cash and cash equivalents	(5,140)	3,497
Cash and cash equivalents at beginning of period	14,055	21,187
Cash and cash equivalents at end of period	\$ 8,915	\$ 24,684
Supplemental cash flow information:		
Interest paid	\$ —	\$ 205
Unpaid issuance costs	\$ —	\$ 26
Property and equipment in accounts payable	\$ —	\$ 4