

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): February 27, 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 ☒

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. ☒

Item 2.02. Results of Operations and Financial Condition.

On February 27, 2020, Obalon Therapeutics, Inc. (the “Company”) reported its financial results for the quarter and year ended December 31, 2019. 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 February 27, 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: February 27, 2020

By:

/s/ Nooshin Hussainy

Nooshin Hussainy

Chief Financial Officer

Obalon Announces Fourth Quarter and Full Year 2019 Financial Results

SAN DIEGO, CA February 27, 2020 (GLOBE NEWSWIRE) -- Obalon Therapeutics, Inc. (NASDAQ: OBLN), a vertically integrated medical technology 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 fourth quarter and full year ended December 31, 2019.

“2019 was an eventful year for Obalon as we recapitalized and repositioned the business to efficiently leverage our FDA-approved weight loss system through our new retail treatment center business model,” said Bill Plovanic, President and Chief Executive Officer. “We are very pleased with the opening and initial operations of our first treatment center in San Diego California, in addition to the recent opening of our second treatment center in Orange County, California. Our priorities in 2020 are focused on expanding our retail treatment center footprint, raising awareness of the Obalon Centers for Weight Loss™ brand, and working to create shareholder value by building a standardized, repeatable business using the Company-owned or managed retail treatment center model.”

Key Accomplishments in 2019:

- Opened the first Obalon-managed retail treatment center in San Diego
- Commercialized Obalon Navigation System and Obalon Touch Inflation Dispenser
- Streamlined operations and spend to support new commercial strategy
- Repaid all outstanding long-term debt
- Promoted Bill Plovanic from Chief Financial Officer to President and Chief Executive Officer
- Appointed Bob MacDonald as Chief Retail Officer to establish and grow our network of Obalon Centers for Weight Loss facilities
- Promoted Nooshin Hussainy from Vice President of Finance to Chief Financial Officer
- Engaged Helmuth T. Billy, MD as Medical Director for Company-managed California retail treatment centers
- Entered into one-year distribution agreement with distributor for Qatar
- Announced clinical data presentation at ASMBS annual meeting at Obesity Week 2019 demonstrating clinically meaningful weight loss for patients treated with the Obalon Balloon System with no serious adverse events reported

Fourth Quarter 2019 Results:

The Company reported revenue of \$0.8 million for the fourth quarter of 2019, compared to \$2.0 million for the fourth quarter of 2018. U.S. revenue of \$0.5 million represented 62% of revenue as compared to \$0.8 million and 41% of revenue in the fourth quarter of 2018. International revenue

of \$0.3 million represented 38% of revenue in the fourth quarter of 2019, compared to \$1.2 million and 59% of revenue in the fourth quarter of 2018.

Cost of revenue was \$0.6 million during the three months ended December 31, 2019, down from \$1.5 million for the prior-year comparable period. Gross profit for the fourth quarter of 2019 was \$0.2 million, resulting in a gross margin of 20%, compared to a gross profit of \$0.5 million and gross margin of 26% for the fourth quarter of 2018.

Research and development expense for the fourth quarter of 2019 totaled \$1.5 million, down from \$2.3 million in the fourth quarter of 2018. Selling, general and administrative expense decreased to \$3.6 million for the fourth quarter of 2019, compared to \$6.9 million in the fourth quarter of 2018.

Operating loss for the fourth quarter of 2019 was \$5.0 million, compared to an operating loss of \$8.7 million for the fourth quarter of 2018.

Net loss in the fourth quarter of 2019 was \$4.9 million, compared to a net loss of \$8.8 million in the fourth quarter of 2018. The net loss per share was \$0.64 for the fourth quarter of 2019 as compared to the net loss per share of \$3.87 for the fourth quarter of 2018.

As of December 31, 2019, Obalon had cash and cash equivalents of \$14.1 million and no outstanding debt.

Full Year 2019 Results:

Obalon reported full year 2019 revenue of \$3.3 million, as compared to \$9.1 million for the full year 2018. U.S. revenue of \$2.4 million represented 73% of full year 2019 revenue, decreasing from \$4.7 million or 52% of full year 2018 revenue. International revenue of \$0.9 million in 2019 equated to 27% of full year 2019 revenue as compared to \$4.4 million of international revenue in 2018 which equated to 48% of full year 2018 revenue.

Gross profit for the full year 2019 was \$0.3 million, resulting in a gross margin of 10%, as compared to \$3.7 million for the full year 2018 and a gross margin of 40%.

Research and development expense totaled \$6.9 million for the full year 2019, as compared to \$10.7 million for the full year 2018. Selling, general and administrative expense decreased to \$16.7 million for the full year 2019, as compared to \$29.9 million for the full year 2018.

Operating loss for the full year 2019 was \$23.2 million, compared to an operating loss of \$37.0 million for the full year 2018.

Net loss was reported at \$23.7 million for the full year 2019 compared to a net loss of \$37.4 million for the full year 2018. The net loss per share was \$5.03 for the full year 2019, as compared to the net loss per share of \$19.64 for the full year 2018.

Call Information

A conference call to discuss fourth quarter and full year 2019 financial results is scheduled for today, February 27, 2020, at 8:30 AM Eastern Time (5:30 AM Pacific Time). Interested parties may access the conference call by dialing (844) 889-7791 (U.S.) or (661) 378-9934 (international) using passcode 6573298. Media and individuals will be in a listen-only mode. Participants are asked to dial in a few minutes prior to the call to register for the event. The conference call will also be webcast live at: <https://edge.media-server.com/mmc/p/c8zmkz5x>. An archive of the webcast will be available for twelve months following the event on the Obalon Therapeutics, Inc. website located at <http://investor.obalon.com> in the “News & Events” section.

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, as filed with the Securities and Exchange Commission on February 27, 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.

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 www.obalon.com.

For Obalon Therapeutics, Inc.

Investor Contact:

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(Unaudited)			
Revenue	\$ 787	\$ 2,036	\$ 3,281	\$ 9,101
Cost of revenue	627	1,504	2,950	5,423
Gross profit	160	532	331	3,678
Operating expenses:				
Research and development	1,492	2,338	6,893	10,697
Selling, general and administrative	3,643	6,854	16,668	29,946
Total operating expenses	5,135	9,192	23,561	40,643
Loss from operations	(4,975)	(8,660)	(23,230)	(36,965)
Interest income (expense), net	63	(62)	(385)	(226)
Other expense	(1)	(34)	(61)	(189)
Net loss	(4,913)	(8,756)	(23,676)	(37,380)
Other comprehensive income	—	2	—	5
Net loss and comprehensive loss	<u>\$ (4,913)</u>	<u>\$ (8,754)</u>	<u>\$ (23,676)</u>	<u>\$ (37,375)</u>
Net loss per share, basic and diluted	<u>\$ (0.64)</u>	<u>\$ (3.87)</u>	<u>\$ (5.03)</u>	<u>\$ (19.64)</u>
Weighted-average common shares outstanding, basic and diluted	<u>7,692,673</u>	<u>2,259,645</u>	<u>4,706,775</u>	<u>1,903,734</u>

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

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,055	\$ 21,187
Short-term investments	—	2,548
Accounts receivable, net	285	870
Inventory	1,936	1,580
Other current assets	1,959	2,462
Total current assets	<u>18,235</u>	<u>28,647</u>
Lease right-of-use assets	1,077	—
Property and equipment, net	1,081	1,739
Total assets	<u>\$ 20,393</u>	<u>\$ 30,386</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 648	\$ 1,159
Accrued compensation	820	3,805
Deferred revenue	424	352
Other current liabilities	1,524	1,985
Current portion of lease liabilities	561	—
Current portion of long-term loan	—	9,930
Total current liabilities	<u>3,977</u>	<u>17,231</u>
Lease liabilities long term	567	—
Other long-term liabilities	—	48
Total liabilities	<u>4,544</u>	<u>17,279</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2019 and December 31, 2018; 7,724,100 and 2,351,333 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	8	2
Additional paid-in capital	188,271	161,859
Accumulated deficit	(172,430)	(148,754)
Total stockholders' equity	<u>15,849</u>	<u>13,107</u>
Total liabilities and stockholders' equity	<u>\$ 20,393</u>	<u>\$ 30,386</u>

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

	Year Ended December 31,	
	2019	2018
Operating activities:		
Net loss	\$ (23,676)	\$ (37,380)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	479	581
Stock-based compensation	2,983	4,693
Amortization of right-of-use asset	415	—
Loss on disposal of fixed assets	128	107
Accretion of investment discount, net	(2)	(50)
Amortization of debt discount	70	37
Change in operating assets and liabilities:		
Accounts receivable, net	585	3,353
Inventory	12	(162)
Other current assets	411	98
Accounts payable	(543)	70
Accrued compensation	(2,985)	(689)
Deferred revenue	72	(158)
Lease liabilities, net	(364)	—
Other current and long term liabilities	(451)	68
Net cash used in operating activities	(22,866)	(29,432)
Investing activities:		
Purchases of short-term investments	—	(9,102)
Maturities of short-term investments	2,550	29,901
Purchases of property and equipment	(194)	(1,282)
Net cash provided by investing activities	2,356	19,517
Financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	23,377	9,823
Proceeds from long-term loan, net of issuance costs	10,000	—
Fees paid in connection with loan amendment	—	(30)
Repayments of long-term loans	(20,000)	—
Proceeds from common stock issued under employee stock purchase plan	—	148
Proceeds from sale of common stock upon exercise of stock options	1	53
Net cash provided by financing activities	13,378	9,994
Net (decrease) increase in cash and cash equivalents	(7,132)	79
Cash and cash equivalents at beginning of period	21,187	21,108
Cash and cash equivalents at end of period	\$ 14,055	\$ 21,187
Supplemental cash flow information:		
Interest paid	\$ 719	\$ 642
Income taxes paid	\$ —	\$ 7
Property and equipment in accounts payable	\$ 32	\$ 201
Unpaid issuance costs	\$ —	\$ 250
Fair value of commitment shares issued	\$ —	\$ 595