

**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 22, 2019

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))

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 22, 2019, Obalon Therapeutics, Inc. (the “Company”) reported its financial results for the quarter and year ended December 31, 2018. 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 22, 2019.

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 22, 2019

By:

/s/ William Plovanic

William Plovanic
Chief Financial Officer

Obalon Announces Fourth Quarter and Full Year 2018 Financial Results

SAN DIEGO, CA February 22, 2019 (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 audited financial results for the fourth quarter and full year ended December 31, 2018.

Key Accomplishments in 2018:

- Full year 2018 revenue of \$9.1 million
- Full year 2018 U.S. revenue of \$4.7 million
- U.S. reorders accounted for approximately 74% of total U.S. revenue
- Presented and published key weight loss and safety data for ~1,300 patients at >100 treatment sites at the ASMBS 2018 Annual Meeting and in the medical journal *Surgery for Obesity and Related Diseases*, respectively
- U.S. FDA Approval of Obalon Navigation System, which is intended to ease adoption for physicians and clinics that do not have ready access to x-ray imaging
- U.S. FDA Approval of Obalon Touch Inflation Dispenser, which is intended to automate balloon inflation and improve ease of use

Fourth Quarter 2018 Results:

The Company reported revenue of \$2.0 million for the fourth quarter of 2018, compared to \$3.7 million for the fourth quarter of 2017. U.S. revenue of \$0.8 million represented 41% of revenue as compared to \$2.9 million and 77% of revenue in the fourth quarter of 2017. International revenue of \$1.2 million represented 59% of revenue in the fourth quarter of 2018, compared to \$0.8 million and 23% of revenue in the fourth quarter of 2017.

Cost of goods sold was \$1.5 million during the three months ended December 31, 2018, down from \$1.7 million for the prior-year comparable period. Gross profit for the fourth quarter of 2018 was \$0.5 million, resulting in a gross margin of 26%, compared to a gross profit of \$2.0 million and gross margin of 54% for the fourth quarter of 2017.

Research and development expense for the fourth quarter of 2018 totaled \$2.3 million, down from \$2.7 million in the fourth quarter of 2017. Selling, general and administrative expense decreased to \$6.9 million for the fourth quarter of 2018, compared to \$9.2 million in the fourth quarter of 2017.

Operating loss for the fourth quarter of 2018 was \$8.7 million, compared to an operating loss of \$9.9 million for the fourth quarter of 2017.

Net loss in the fourth quarter of 2018 was \$8.8 million, compared to a net loss of \$10.1 million in the fourth quarter of 2017. The net loss per share was \$0.39 for the fourth quarter of 2018 as compared to the net loss per share of \$0.60 for the fourth quarter of 2017.

As of December 31, 2018, Obalon had cash, cash equivalents and short-term investments of \$23.7 million and total debt of \$10.0 million. During the first quarter of 2019, the Company subsequently drew down the remaining \$10.0 million available under its term loan, for total debt outstanding of \$20.0 million.

Full Year 2018 Results

Obalon reported full year 2018 revenue of \$9.1 million, as compared to \$9.9 million for the full year 2017. U.S. revenue of \$4.7 million represented 52% of full year 2018 revenue, decreasing from \$8.3 million or 83% of full year 2017 revenue. International revenue of \$4.4 million in 2018 equated to 48% of full year 2018 revenue as compared to \$1.6 million of international revenue in 2017 which equated to 17% of full year 2017 revenue.

Gross profit for the full year 2018 was \$3.7 million, resulting in a gross margin of 40%, as compared to \$5.1 million for the full year 2017 and a gross margin of 51%.

Research and development expense totaled \$10.7 million for the full year 2018, as compared to \$10.6 million for the full year 2017. Selling, general and administrative expense increased to \$29.9 million for the full year 2018, as compared to \$28.8 million for the full year 2017.

Operating loss for the full year 2018 was \$37.0 million, compared to an operating loss of \$34.4 million for the full year 2017.

Net loss was reported at \$37.4 million for the full year 2018 compared to a net loss of \$34.8 million for the full year 2017. The net loss per share was \$1.96 for the full year 2018, as compared to the net loss per share of \$2.08 for the full year 2017.

Call Information

A conference call to discuss fourth quarter and full year 2018 financial results is scheduled for today, February 22, 2019, 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

4889307. 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: <http://edge.media-server.com/m6/p/58t82ok5>.

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, 2018, as filed with the Securities and Exchange Commission on February 22, 2019, 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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Chief Financial Officer

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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,	
	2018	2017	2018	2017
	(Unaudited)			
Revenue	\$ 2,036	\$ 3,692	\$ 9,101	\$ 9,914
Cost of revenue	1,504	1,702	5,423	4,829
Gross profit	532	1,990	3,678	5,085
Operating expenses:				
Research and development	2,338	2,689	10,697	10,647
Selling, general and administrative	6,854	9,223	29,946	28,829
Total operating expenses	9,192	11,912	40,643	39,476
Loss from operations	(8,660)	(9,922)	(36,965)	(34,391)
Interest expense, net	(62)	(25)	(226)	(135)
Other expense	(34)	(173)	(189)	(239)
Net loss	(8,756)	(10,120)	(37,380)	(34,765)
Other comprehensive income (loss)	2	—	5	(4)
Total comprehensive loss	\$ (8,754)	\$ (10,120)	\$ (37,375)	\$ (34,769)
Net loss per share, basic and diluted	\$ (0.39)	\$ (0.60)	\$ (1.96)	\$ (2.08)
Weighted-average common shares outstanding, basic and diluted	22,595,768	16,918,702	19,036,693	16,717,106

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,187	\$ 21,108
Short-term investments	2,548	23,292
Accounts receivable, net	870	4,223
Inventory	1,580	1,418
Other current assets	2,462	1,714
Total current assets	28,647	51,755
Property and equipment, net	1,739	1,346
Total assets	\$ 30,386	\$ 53,101
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,159	\$ 1,276
Accrued compensation	3,805	4,494
Deferred revenue	352	510
Other current liabilities	1,985	1,773
Current portion of long-term loan	9,930	1,958
Total current liabilities	17,231	10,011
Deferred rent	48	13
Long-term loan, excluding current portion	—	7,964
Total long-term liabilities	48	7,977
Total liabilities	17,279	17,988
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 and 300,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 23,513,292 and 17,500,604 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	23	18
Additional paid-in capital	161,838	146,474
Accumulated other comprehensive loss	—	(5)
Accumulated deficit	(148,754)	(111,374)
Total stockholders' equity	13,107	35,113
Total liabilities and stockholders' equity	\$ 30,386	\$ 53,101

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

	Year Ended December 31,	
	2018	2017
	(Unaudited)	
Operating activities:		
Net loss	\$ (37,380)	\$ (34,765)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	581	330
Stock-based compensation	4,693	3,241
Fair value of stock issued for legal settlement	—	1,606
Loss on disposal of fixed assets	107	—
(Accretion) amortization of investment (discount) premium, net	(50)	18
Amortization of debt discount	37	42
Change in operating assets and liabilities:		
Accounts receivable, net	3,353	(4,223)
Accounts receivable from related party	—	515
Inventory	(162)	(591)
Other current assets	98	(470)
Accounts payable	70	624
Accrued compensation	(689)	1,997
Deferred revenue	(158)	389
Other current and long term liabilities	68	663
Net cash used in operating activities	<u>(29,432)</u>	<u>(30,624)</u>
Investing activities:		
Purchases of short-term investments	(9,102)	(94,613)
Maturities of short-term investments	29,901	73,800
Purchase of property and equipment	(1,282)	(1,043)
Net cash provided by (used in) investing activities	<u>19,517</u>	<u>(21,856)</u>
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	9,823	—
Fees paid in connection with loan amendment	(30)	—
Proceeds from stock issued under employee stock purchase plan	148	429
Proceeds from sale of common stock upon exercise of stock options	53	184
Net cash provided by financing activities	<u>9,994</u>	<u>613</u>
Net increase (decrease) in cash and cash equivalents	79	(51,867)
Cash and cash equivalents at beginning of period	21,108	72,975
Cash and cash equivalents at end of period	<u>\$ 21,187</u>	<u>\$ 21,108</u>
Supplemental cash flow information:		
Interest paid	<u>\$ 642</u>	<u>\$ 562</u>
Income taxes paid	<u>\$ 7</u>	<u>\$ 2</u>
Property and equipment in accounts payable	<u>\$ 201</u>	<u>\$ 83</u>
Fair value of commitment shares issued	<u>\$ 595</u>	<u>\$ —</u>
Unpaid issuance costs	<u>\$ 250</u>	<u>\$ —</u>