

**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): November 2, 2018

OBALON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001- 37897

**(Commission
File Number)**

20-1828101

**(IRS Employer
Identification No.)**

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

(Address of principal executive offices)

92008

(Zip Code)

(760) 795-6558

(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 November 2, 2018 Obalon Therapeutics, Inc. (the “Company”) reported its financial results for the three and nine months ended September 30, 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 5.02. Appointment of Certain Officers.

On November 1, 2018, as part of a planned succession the Board of Directors (the “Board”) of the Company approved the appointment of Kelly Huang, Ph.D., age 49, as the Company’s Chief Executive Officer, effective as of January 2, 2019. In addition to his appointment as the Company’s Chief Executive Officer, Dr. Huang will retain the title of President and will be appointed to serve as a Class III director on the Board, also effective as of January 2, 2019. Coincident with the promotion of Dr. Huang to Chief Executive Officer, Andrew Rasdal will transition to Chairman of the Board and plans to remain actively involved as a resource to Dr. Huang and to focus on several key strategic projects to help build the intragastric balloon market and create sustainable value for Obalon.

Information regarding Dr. Huang’s background, business experience and any related party transactions appears in the Company’s Definitive Proxy Statement on Schedule 14A, filed with the Securities and Exchange Commission on April 30, 2018 under the headings “Executive Officers” and “Certain Relationships and Related Party Transactions,” which information is incorporated herein by reference. There are no family relationships between Dr. Huang and any of the Company’s directors or executive officers.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit Number	Description
99.1	Press Release dated November 2, 2018

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: November 2, 2018

By:

/s/ William Plovanic

William Plovanic

Chief Financial Officer

Obalon Announces Third Quarter 2018 Financial Results

SAN DIEGO, CA November 2, 2018 (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 unaudited financial results as of and for the third quarter ended September 30, 2018.

Third Quarter 2018 highlights:

- Total revenue of \$3.0 million increased 9% vs Q2-18
- US revenue of \$1.8 million increased 17% vs Q2-18
- US Reorders were \$1.4 million, or 79% of US sales, an increase of 45% vs Q2-18
- Gross margin of 53% increased from 37% in Q2-18
- Operating loss of \$6.6 million improved 31% vs \$9.6 million in Q2-18
- Net cash use of \$5.5 million decreased 33% vs. use of \$8.3 million in Q2-18
- Completed Private Placement raising gross proceeds of \$10.0 million
- Received FDA PMA-S approval for the Obalon Touch Inflation System
- As part of a planned succession, on January 2, 2019 the Company will transition Kelly Huang, Ph.D. to the role of Chief Executive Officer and Andy Rasdal to the role of Chairman of the Board

The Company reported revenue of \$3.0 million for the third quarter of 2018, compared to \$2.7 million for the second quarter of 2018 and \$2.8 million for the third quarter of 2017. Net loss was reported at \$6.7 million for the third quarter of 2018, compared to \$9.8 million for the second quarter of 2018 and \$9.2 million for the third quarter of 2017. Net loss per share for the third quarter of 2018 was \$0.35 as compared to \$0.57 for the second quarter of 2018 and \$0.55 for the third quarter of 2017.

Cost of revenue was \$1.4 million for the third quarter of 2018, down from \$1.7 million for the second quarter of 2018, and up from \$1.3 million for third quarter of 2017. Gross profit for the third quarter of 2018 was \$1.6 million, resulting in a gross margin of 53%, compared to a gross

profit of \$1.0 million and gross margin of 37% for the second quarter of 2018 and a gross profit of \$1.5 million and gross margin of 53% for the third quarter of 2017.

Research and Development expense for the third quarter of 2018 totaled \$2.4 million, down from \$3.4 million for the second quarter of 2018 and \$2.8 million for the third quarter of 2017. Selling, General and Administrative expense decreased to \$5.8 million for the third quarter of 2018 as compared to \$7.3 million for the second quarter of 2018 and \$7.8 million for the third quarter of 2017.

Operating loss for the third quarter of 2018 was \$6.6 million, down from \$9.6 million for the second quarter of 2018 and \$9.1 million for the third quarter of 2017.

As of September 30, 2018, cash, cash equivalents and short-term investments were \$29.7 million.

Call Information

A conference call to discuss third quarter 2018 financial results is scheduled for today, November 2, 2018, 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 6045357. 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/m6/p/7sfacf89>.

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.

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. The Obalon management team has over 150 combined years of experience in developing and commercializing novel medical technologies with a track record of financial and clinical excellence. For more information, please visit <http://www.obalon.com>.

For Obalon Therapeutics, Inc.

Investor Contact:

William Plovanic

Chief Financial Officer
Obalon Therapeutics, Inc.
Office: +1 760 607 5103
wplovanic@obalon.com

Media:
Megan Driscoll
EvolveMKD
Office Phone: +1 646 517 4220
mdriscoll@evolvemkd.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)			
Revenue	\$ 2,987	\$ 2,787	\$ 7,065	\$ 6,222
Cost of revenue	1,418	1,314	3,919	3,127
Gross profit	1,569	1,473	3,146	3,095
Operating expenses:				
Research and development	2,368	2,798	8,359	7,958
Selling, general and administrative	5,836	7,813	23,092	19,606
Total operating expenses	8,204	10,611	31,451	27,564
Loss from operations	(6,635)	(9,138)	(28,305)	(24,469)
Interest expense, net	(70)	(21)	(164)	(110)
Other expense	(40)	(11)	(155)	(66)
Net loss	(6,745)	(9,170)	(28,624)	(24,645)
Other comprehensive (loss) income	(3)	15	3	(3)
Total comprehensive loss	\$ (6,748)	\$ (9,155)	\$ (28,621)	\$ (24,648)
Net loss per share, basic and diluted	\$ (0.35)	\$ (0.55)	\$ (1.60)	\$ (1.48)
Weighted-average common shares outstanding, basic and diluted	19,457,971	16,747,791	17,837,297	16,649,447

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

	September 30, 2018	December 31, 2017
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,552	\$ 21,108
Short-term investments	8,116	23,292
Accounts receivable, net of allowance of \$538 and \$239, respectively	2,775	4,223
Inventory	1,955	1,418
Other current assets	909	1,714
Total current assets	<u>35,307</u>	<u>51,755</u>
Property and equipment, net	1,572	1,346
Total assets	<u><u>\$ 36,879</u></u>	<u><u>\$ 53,101</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,458	\$ 1,276
Accrued compensation	2,671	4,494
Deferred revenue	301	510
Other current liabilities	2,328	1,773
Current portion of long-term loan	523	1,958
Total current liabilities	<u>7,281</u>	<u>10,011</u>
Deferred rent	46	13
Long-term loan, excluding current portion	9,399	7,964
Total long-term liabilities	<u>9,445</u>	<u>7,977</u>
Total liabilities	<u>16,726</u>	<u>17,988</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 and 300,000,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively; 23,280,310 and 17,500,604 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	23	18
Additional paid-in capital	160,130	146,474
Accumulated other comprehensive loss	(2)	(5)
Accumulated deficit	(139,998)	(111,374)
Total stockholders' equity	<u>20,153</u>	<u>35,113</u>
Total liabilities and stockholders' equity	<u><u>\$ 36,879</u></u>	<u><u>\$ 53,101</u></u>

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

	Nine Months Ended September 30,	
	2018	2017
	(Unaudited)	
Operating activities:		
Net loss	\$ (28,624)	\$ (24,645)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	428	221
Stock-based compensation	3,610	2,102
Fair value of stock issued for legal settlement	—	1,398
Loss on disposal of fixed assets	107	—
(Accretion) amortization of investment (discount) premium, net	(20)	24
Amortization of debt discount	29	31
Change in operating assets and liabilities:		
Accounts receivable, net	1,448	(2,515)
Accounts receivable from related party	—	515
Inventory	(537)	(84)
Other current assets	805	240
Accounts payable	135	534
Accrued compensation	(1,823)	174
Deferred revenue	(209)	72
Other current and long term liabilities	634	506
Net cash used in operating activities	(24,017)	(21,427)
Investing activities:		
Purchases of short-term investments	(9,103)	(80,317)
Maturities of short-term investments	24,302	41,500
Purchase of property and equipment	(867)	(904)
Net cash provided by (used in) investing activities	14,332	(39,721)
Financing activities:		
Fees paid in connection with loan amendment	(30)	—
Proceeds from issuance of common stock, net of issuance costs	9,973	—
Proceeds from stock issued under employee stock purchase plan	148	210
Proceeds from sale of common stock upon exercise of stock options	38	46
Net cash provided by financing activities	10,129	256
Net increase (decrease) in cash and cash equivalents	444	(60,892)
Cash and cash equivalents at beginning of period	21,108	72,975
Cash and cash equivalents at end of period	\$ 21,552	\$ 12,083
Supplemental cash flow information:		
Interest paid	\$ 473	\$ 416
Unpaid issuance costs	\$ 160	\$ —
Property and equipment in accounts payable	\$ 106	\$ 126