

**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): January 3, 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)**

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

Item 2.02 Results of Operations and Financial Condition

On January 3, 2019, Obalon Therapeutics, Inc. (the “Company” or “Obalon”) hosted a conference call to discuss its receipt of FDA approval for the Obalon Navigation System and to provide an update on its anticipated 2018 results of operations. During that call, the Company:

- re-affirmed its full-year 2018 revenue guidance of \$9.0 million to \$9.9 million and its U.S. sales guidance of between \$4.6 million and \$5.5 million;
- noted that it expects global sales to be at the low end of the guidance range for the full year, as it did not expect to receive any revenue from Sono Bello in the fourth quarter, and that the low-end revenue would negatively impact gross margin in the fourth quarter of 2018;
- stated that it expects to have shipped 10 new starter kits in the fourth quarter of 2018, which is consistent with its more focused targeting strategies, and that it expects reorders from existing accounts to represent the largest component of its U.S. revenue for the fourth quarter and full year 2018; and
- indicated that it expects sales to Bader Sultan & Bros. Co. W.L.L., its Middle East distributor, for the full-year 2018 to be approximately \$4.4 million, consistent with its prior guidance. The Company also noted that it does not intend to ship product to Bader or to generate any non-U.S. revenue after the first quarter of 2019. Its agreement with Bader expires at the end of 2019 and the Company does not intend to automatically renew.

The Company plans to provide guidance for 2019 when it reports its final results of operations for the fourth quarter and full year 2018 in February 2019.

The information in Item 2.02 of this Current Report on Form 8-K 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 to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events

In connection with business updates provided during the conference call on January 3, 2019, the Company is also updating its summary business section, which was most recently included in its prospectus supplement filed on December 27, 2018, to read as set forth Exhibit 99.1. Exhibit 99.1 also updates a risk factor that previously appeared in the quarterly report on Form 10-Q for the quarter ended September 30, 2018.

Cautionary note regarding forward-looking statements

The Items discussed in this Current Report on Form 8-K and the exhibits thereto contain forward-looking statements. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Current Report on Form 8-K. These forward-looking statements may include, but are not limited to, statements regarding the Company’s future results of operations and financial position, business strategy, market size, potential growth opportunities, timing and results of preclinical and clinical development activities, 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.

The Company has based these forward-looking statements largely on its current expectations and projections about future events and trends that the Company believes may affect its 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 herein and in the “Risk Factors” section and elsewhere in Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. Moreover, the Company operates in a very competitive and rapidly changing environment, and new risks emerge from

time to time. It is not possible for the Company’s management to predict all risks, nor can the Company assess the impact of all factors on its 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 it may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Current Report on Form 8-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The Company undertakes 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Updated business and related disclosures

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: January 3, 2019

By: /s/ William Plovanic

William Plovanic

Chief Financial Officer

Summary Business Description

This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information you should consider before investing in our common stock pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including “Risk Factors” beginning on page S-6 of this prospectus supplement, the financial statements and related notes, and the other information that we incorporate by reference into this prospectus supplement, including the section “Risk Factors” in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018. As used in this prospectus supplement, unless the context requires otherwise, the terms “Company,” “we,” “our” and “us” refer to Obalon Therapeutics, Inc., unless otherwise specified.

Our Business

We are a vertically integrated medical device company focused on developing and commercializing innovative medical devices to treat obese and overweight people. Our initial 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 obese patients. We believe the Obalon balloon system offers patients and physicians benefits over prior weight loss devices including, but not limited to: a favorable safety profile, improved patient tolerability and comfort, progressive weight loss with durable results, simple and convenient placement, and potentially attractive economics for patients and physicians.

In September 2016, we received premarket approval, or PMA, from the FDA, and commenced U.S. commercialization in January 2017 through a direct sales force. The Obalon balloon system is FDA approved for temporary use to facilitate weight loss in obese adults with 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 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. The Obalon balloon system has the potential to provide patients and physicians with a cost-effective, reversible and repeatable weight loss solution in an outpatient setting, without altering patient anatomy or requiring surgery.

In November 2017, we submitted a PMA supplement to the FDA for our Obalon Touch™ Inflation Dispenser, also known as Obalon Touch. The Obalon Touch is our next generation inflation system that is designed to be automated, easier to operate and to provide more reliable and consistent Obalon balloon placement. In September 2018, we received approval of a PMA supplement from the FDA for our Obalon Touch Inflation System.

In July 2018, we submitted a PMA supplement to the FDA for our Obalon Navigation System. The Obalon Navigation System is designed to eliminate the need to use x-ray when placing the Obalon Balloon System. It utilizes magnetic resonance, rather than x-ray radiation, to image the Obalon Balloon during placement and displays a dynamic, real-time image of the Balloon on a notebook computer screen. In December 2018, we received approval of a PMA supplement from the FDA for our Obalon Navigation System. The Obalon Navigation System will be utilized in conjunction with the new, automated Touch Inflation Dispenser, and together they are intended to make placement of the Obalon Balloon more reliable, safer, easier and less expensive. We expect to make the Obalon Navigation System and Touch Inflation Dispenser commercially available during the first quarter of 2019 in the United States. As part of the FDA approval, we have agreed to a post approval study where we will collect and report data around acute balloon placements with the Navigation System, similar to the acute placement study we conducted and filed to support FDA approval of the Obalon Navigation System with Touch Dispenser.

We are selling the Obalon balloon system on a self-pay, non-reimbursed basis into existing physician specialty areas with weight loss practices, such as bariatric surgeons and gastroenterologists. In addition, we are selling to plastic surgeons, due to their client base and experience managing self-pay practices. Physicians can market our product as a highly differentiated, non-surgical weight loss procedure. Based on our product design and commercial data, we believe the Obalon balloon system provides potentially attractive economics for patients and physicians. We expect to continue to focus our sales and marketing efforts primarily on selling our product in the United States through a direct sales force. In the second half of 2018, we revised the field sales team structure to support our customers more efficiently.

We also intend to continue to drive patient awareness and interest in part through multiple efforts that may include digital, offline and social marketing, as well as public relations efforts targeted to obtain online and offline media coverage.

Intragastric balloons represent a relatively new category of treatment for weight loss in the United States and the current market is small and immature. Our strategy is to methodically build the foundation to establish the Obalon balloon system as an important, growing and sustainable treatment for weight loss. We are currently employing a focused launch strategy to ensure our initial target accounts achieve clinical and economic success before launching more broadly in the U.S. and international markets. We expect to continue investing in various activities to develop the intragastric balloon market for the foreseeable future.

The Obalon Navigation System

The Obalon Navigation System consists of a Navigation console, and the Touch Inflation Dispenser. The Obalon Navigation Balloon is placed utilizing the Obalon Navigation console and Touch Dispenser.

- The Obalon Navigation console is a portable device consisting of hardware and software that are used to track and display the Navigation Balloon during administration. The console has a significantly smaller footprint than most x-ray systems currently used by physicians when placing balloons and does not require any special facilities or licensing.
- The Obalon Balloons administered with the Navigation System are identical to the current balloons but utilize a new catheter. The new catheter interfaces with the Navigation Console to dynamically track the balloon during placement.
- The Touch Inflation Dispenser is a semi-automated, hand-held inflation device that provides real-time balloon pressure measurements to confirm that the Obalon balloon is both properly placed and correctly inflated in the stomach. The Navigation System will be commercially launched exclusively with the Touch Dispenser. The existing balloon system kits are not compatible with the Navigation System or the Touch Dispenser and must continue to be placed using x-ray. However, because the balloon is the same in both systems, physicians may provide treatment with a current generation balloon and transition to the new Navigation balloon for second or third balloon administrations. We believe this will enable physicians to manage any existing inventory as they transition to the Navigation System.

While we have several initiatives intended to reduce the manufacturing costs associated with the Navigation System and help improve gross margin, we expect we may experience some decline in our gross margin upon its initial launch primarily because:

- the Navigation console and the Touch Inflation Dispenser are both new products that we have not yet manufactured at scale and each involves a more complex manufacturing process; and
- we intend to price the Navigation console in a manner that facilitates adoption.

We plan to begin the commercial launch of the Navigation System in the first quarter of 2019. We expect commercial launch will initially focus on targeting potential new accounts where x-ray was a barrier to adoption and existing customers whom we believe could benefit by using navigation to drive higher treatment volumes and improved economics. We intend to initially launch with the same number of territories and field structure as we have in place today. Additionally, we initially plan to continue supplying both our current products and the new Navigation products, but to transition exclusively to Navigation over time.

Updated Risk Factor

Material modifications to our Obalon balloon 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. In these circumstances, we may be subject to significant enforcement actions.