

**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): May 11, 2017

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)

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 8.01 Other Events.

On May 11, 2017, Obalon Therapeutics, Inc. (the "Company") announced that it received notification that it has obtained the necessary regulatory approvals in select Middle East markets to commercialize the Obalon six-month balloon and the associated inflation dispenser. The Company intends to fulfill an initial order to its Middle East distributor, Bader Sultan, during the second quarter of 2017.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding when the Company intends to fulfill an initial order to its Middle East distributor, Bader Sultan. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements. Forward-looking statements are subject to risks and uncertainties that may cause the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the Company's ability to achieve or sustain profitability; the Company's ability to predict its future prospects and forecast its financial performance and growth; the rate at which physicians and patients adopt and use the Company's balloon system; the effect of adverse events or other negative developments involving other companies' intragastric balloons or other obesity treatments; the Company's ability to educate physicians on safe and proper use of the Obalon balloon system; the rate at which patients may experience serious adverse device events as the result of the misuse or malfunction of, or design flaws in, the Company's products; the Company's ability to obtain FDA approval or other regulatory approvals for its future products and product improvements; the Company's ability to adequately protect its proprietary technology and maintain its issued patents and other risks and uncertainties described under the heading "Risk Factors" in documents the Company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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: May 11, 2017

By:

/s/ William Plovanic

William Plovanic

Chief Financial Officer