

**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): September 26, 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))
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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 8.01. Other Events.

On September 26, 2018, Obalon Therapeutics, Inc. (the “Company”) announced approval of a Premarket Approval Supplement application for the Obalon Touch™ Inflation System from the U.S. Food and Drug Administration. The Obalon Touch™ Inflation System is an automated system utilized to inflate the Obalon Balloon.

A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated September 26, 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: September 26, 2018

By: /s/ William Plovanic

William Plovanic

Chief Financial Officer

FDA Grants PMA-S Approval for Obalon Touch[™] Inflation System

SAN DIEGO, CA, September 26, 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 approval of a Premarket Approval Supplement (PMA-S) application for the Obalon Touch[™] Inflation System from the United States Food and Drug Administration (FDA). The Obalon Touch[™] Inflation System is an automated system utilized to inflate the Obalon Balloon.

"We are pleased to have received FDA approval of The Obalon Touch[™] Inflation System," said Amy Vandenberg, Vice President of Clinical and Regulatory Affairs. "Our near-term product pipeline is dedicated to further improving safety, reliability and ease of use of the Obalon Balloon System."

The Obalon Touch[™] is intended to be commercialized in combination with the Obalon Navigation System, which is designed to eliminate the need for X-ray imaging during balloon placement. A PMA-S application for the Obalon Navigation System was filed with the FDA in the third quarter of 2018 and is pending a decision by the FDA.

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 www.obalon.com.

Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Obalon Therapeutics, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements regarding Obalon Therapeutics' near-term product pipeline, the commercialization of Obalon Therapeutics' systems and the status of Obalon Therapeutics'

filings with the FDA. Such statements are subject to substantial risks and uncertainties that could cause Obalon Therapeutics' future results, performance, approvals or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the product research, development and regulatory process and risks. Forward-looking statements speak only as of the date they were made, and Obalon Therapeutics undertakes no obligation to update, review or revise any forward-looking statement. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Obalon Therapeutics' business in general, please refer to Obalon Therapeutics' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 2, 2018, and its current and future periodic reports filed with the Securities and Exchange Commission.

For Obalon Therapeutics, Inc.

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