AMAG PHARMACEUTICALS INC.
Form 8-K
November 13, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 13, 2018

AMAG PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-10865	04-2742593	
(Commission File Number)	(IRS Employer Identification No.)	
1100 Winter St.		
Waltham, Massachusetts		02451
(Address of principal executive offices)		(Zip Code)

(617) 498-3300
(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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.

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Item 7.01. Regulation FD Disclosure.

As part of AMAG Pharmaceuticals, Inc.'s (the "Company") discussions with the U.S. Food and Drug Administration (the "FDA") regarding its review of the New Drug Application ("NDA") submission for Vyleesi™ (bremelanotide), the FDA has requested that additional data be generated from a small Phase 1 study with premenopausal volunteers assessing 24-hour ambulatory blood pressure with short term daily use of Vyleesi. As part of its ongoing review, the FDA has indicated that these data are required to help better characterize the impact of frequent dosing, including to help inform the Vyleesi label. The Company believes that this study can be conducted and data submitted prior to March 23, 2019, the currently scheduled Prescription Drug User Fee Act ("PDUFA") date. The FDA will assess the need for an Advisory Committee meeting after receipt and review of the requested data, and has informed the Company that the previously communicated January 2019 Advisory Committee meeting will not take place. Although the Company's discussions to date with the FDA are preliminary, and the Company will continue to have further discussions with the FDA on this matter, the Company believes that this submission of additional data could cause a delay of the potential approval of Vyleesi by three to six months.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein or therein which do not describe historical facts, including, among others, expectations as to the FDA's requests and study requirements; beliefs that the additional study can be conducted and data submitted prior to the PDUFA date and the impact on the timeline of the potential approval of Vyleesi; and expectations as to further discussions with the FDA are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, among others, the fact that discussions with FDA regarding the Vyleesi NDA are ongoing and, accordingly, FDA may require additional or more comprehensive study data and the risk that the costs associated with such efforts will be higher than anticipated, as well as those risks identified in AMAG's filings with the U.S. Securities and Exchange Commission (the "Commission"), including its Annual Report on Form 10-K for the year ended December 31, 2017 and subsequent filings with the Commission, including the Company's Quarterly Reports on Form 10-Q for the quarters ended June 30, 2018 and September 30, 2018, which are available at the Commission's website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect AMAG's results of operations, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on AMAG's stock price. AMAG cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. AMAG disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

SIGNATURES

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.

AMAG PHARMACEUTICALS, INC.
By: /s/ Joseph D. Vittiglio
Joseph D. Vittiglio
Executive Vice President, General Counsel, Quality & Corporate Secretary
Dated: November 13, 2018