AMAG PHARMACEUTICALS INC.
Form 8-K
November 02, 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 1, 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.

The following information and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, except as expressly set forth by specific reference in such filing.

On November 1, 2018, AMAG Pharmaceuticals, Inc. ("AMAG") hosted a quarterly conference call where they discussed AMAG's third quarter 2018 financial results, and also provided an overview of recent business highlights, expectations for 2018 and beyond, and other business matters. A copy of the transcript of the call is furnished herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

AMAG hereby furnishes the following exhibit:

Exhibit Number	Description
99.1	Earnings call transcript, dated November 1, 2018.

This report and Exhibit 99.1 contain 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 for Feraheme® pricing and market share; beliefs about Feraheme's resiliency to INFeD®; beliefs about the conversion from the Makena® intramuscular to sub-cutaneous ("SC") auto-injector; plans to protect the Makena brand by continued conversion to the SC auto-injector and patient access; expectations about supply of Makena, including when additional supply will be available; beliefs about generic economics; beliefs about Intrarosa® market share; beliefs about Intrarosa media coverage and marketing initiatives; expectations for 2018 financial guidance, including revenues, operating loss and adjusted EBITDA; expectations that the fourth quarter will be a period of continued investment to drive future value; AMAG's key expectations and themes for 2019, including preliminary estimates of EBITDA, product revenue growth, a decline in Makena IM revenues and the belief that Makena SC auto-injector will be sustainable, the planned launch of Vylessi™ (if approved), increased investments in AMAG-423, Vyleesi and Intrarosa and capital allocations from AMAG's balance sheet to fuel its investments; beliefs that AMAG's balance sheet is strengthening; beliefs about stockholder value and AMAG's portfolio; beliefs about annual peak revenue opportunities for AMAG-423, Vyleesi and Intrarosa; beliefs about preeclampsia, the market for, and the anticipated timeline for the FDA's Advisory Committee meeting for, and launch of, AMAG-423 (if approved); beliefs about the Vyleesi Phase 3 studies, including favorable safety profile; beliefs about the market for, and the anticipated timeline for launch of, Vyleesi (if approved); beliefs about the market for Intrarosa; beliefs that the AMAG portfolio is innovative and plans to deliver multiple value drivers; the anticipated regulatory timeline for AMAG's products and product candidates; and plans to undertake additional licensing and acquisition transactions and the expected areas of such expansion are based on management's current expectations and beliefs and 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 risk that sales of Makena will continue to be negatively impacted by the supply disruption and recent and future generic entries in the market; the risk that AMAG may be unable to gain approval of its product candidates, including Vyleesi and AMAG-423, on a timely basis, or at all; the potential for such approvals, if obtained, to include unanticipated restrictions or warnings and the risk that the costs and time investments for AMAG's development efforts will be higher than anticipated, or that AMAG has

over-estimated the market and potential revenues for its products and product candidates, if approved, including AMAG's beliefs about annual peak sales for AMAG-423, Vyleesi and Intrarosa, 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, 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

Dates: November 2, 2018