AMAG PHARMACEUTICALS INC.
Form 8-K
September 26, 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): September 26, 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 and 99.2 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 September 26, 2018, AMAG Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it had acquired the global rights to develop and market digoxin immune Fab (ovine) for the treatment of severe preeclampsia from Velo Bio, LLC, a privately held life sciences company and its intention to hold a conference call to discuss the acquisition.

A copy of the press release is attached hereto as Exhibit 99.1 and a copy of the presentation slides to be used during the conference call is furnished herewith as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

AMAG hereby furnishes the following exhibits:

Exhibit Number	Description
99.1	Press release entitled “AMAG Pharmaceuticals Acquires Orphan Drug Candidate For Treatment Of Severe Preeclampsia”
99.2	Copy of AMAG Pharmaceuticals, Inc.’s presentation slides dated September 26, 2018.

Forward-Looking Statements

This report contains forward-looking information about AMAG Pharmaceuticals, Inc. within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein which do not describe historical facts, including, among others, AMAG’s expectation that it will announce topline data from the Phase 2b/3a study in the first half of 2020 and submit a new drug application to the FDA in the second half of 2020; the expected development and regulatory timeline for all product candidates; AMAG’s expectations to accelerate the development timeline for the AMAG-423 program, including the number and location of study sites to be opened; beliefs about preeclampsia, including the potential benefits of DIF and the expected market opportunity; AMAG’s beliefs regarding the target product profile for DIF, including the presumed mechanism of action, indication, and safety profile; AMAG’s beliefs that decreasing EDLFs may improve vascular function and lead to better post-delivery outcomes in affected mothers and babies; beliefs that DIF is a natural fit for AMAG based on its’ significant presence in women's healthcare and the evolution of its current portfolio expansion strategy to include innovative development-stage therapeutics; AMAG’s beliefs that DIF could significantly benefit women and their newborns suffering from severe preeclampsia, potentially improve patient outcomes and reduce health care costs; and AMAG’s expectations that the incremental research and development costs associated with advancing the DIF program in 2018 will not impact the financial guidance issued by AMAG on August 2, 2018; beliefs that the proof of concept study demonstrated consistent and encouraging trends and that its current Phase 2b/3a study has potential to form the basis for accelerated approval 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 DIF will not be approved on the expected timeline or at all, including as a result of the clinical trial design and enrollment, or as a result of any safety issues that may arise

as part of such trial; the risk that, even if approved, the market for AMAG-423 may be smaller than expected or AMAG may not be successful in accessing such market or otherwise realize the expected benefits of the acquisition, as well as those risks identified in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K for the year ended December 31, 2017, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and subsequent filings with the SEC. 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: September 26, 2018