AMAG PHARMACEUTICALS INC.
Form 8-K
June 25, 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): June 25, 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 Street
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.

On June 25, 2018, AMAG Pharmaceuticals, Inc. ("AMAG" or the "Company") announced that it intends to launch an authorized generic version of the single-dose intramuscular formulation of Makena® (hydroxyprogesterone caproate injection) into the U.S. market, through its generic partner, Prasco Laboratories ("Prasco"). The Company had previously entered into an agreement with Prasco so that it would be prepared to launch its own authorized generic upon the first entry of a generic Makena product, which AMAG now believes is forthcoming given the recent approval by the U.S. Food and Drug Administration of one generic version of the single-dose intramuscular form. Prasco has product inventory available and will commence contracting and shipping product as soon as authorized by AMAG upon launch of a generic product. A mid-year approval and launch of a generic was anticipated in the Company's 2018 revenue, operating loss and non-GAAP adjusted EBITDA guidance previously disclosed in May 2018. As a result of this partnership, AMAG will be able to provide patients and healthcare providers with access to a therapeutically equivalent version of the branded Makena intramuscular injection.

AMAG also recently launched a Makena subcutaneous auto-injector. The prefilled Makena auto-injector offers an alternative administration option for patients and providers and contains a shorter, thinner non-visible needle compared to the intramuscular Makena injection. Based on the most recent weekly data, approximately 60% of all new patient enrollments through the Makena Care Connection® have been for the Makena subcutaneous auto-injector. Makena and its authorized generic version are indicated to reduce the risk of preterm birth in women who are pregnant with one baby and who spontaneously delivered one preterm baby in the past.

Forward-Looking Statements

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 which do not describe historical facts, including, among others, expectations for generic competition, the Company's generic launch, including timing, patient access, and the impact on forecasted revenues, operating loss and non-GAAP adjusted EBITDA, 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 possibility that additional generics will enter the market, that AMAG and/or Prasco will not be able to successfully commercialize their generic product, that the impact on Makena revenues will be different than expected and the possibility that the Company will not be able to continue to successfully commercialize the subcutaneous auto-injector or meet demand for its products, 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 and subsequent filings with the SEC. Any such risks and uncertainties could materially and adversely affect the Company's results of operations, its projections, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on the Company's stock price. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company 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.

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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 thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

By: /s/ Joseph D. Vittiglio, Esq.
Joseph D. Vittiglio
Executive Vice President, General Counsel, Quality & Corporate Secretary
Date: June 25, 2018