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): **March 8, 2019**

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**	
(Address of principal executive offices)	**02451** (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:

☐ 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))

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. ☐

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 Securities Exchange Act of 1934, as amended (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 of 1933, as amended (the "Securities Act"), except as expressly set forth by specific reference in such filing. On March 8, 2019, AMAG Pharmaceuticals, Inc. ("the Company") issued a press release announcing topline results from PROLONG (Progestin's Role in Optimizing Neonatal Gestation), a randomized, double-blinded, placebo-controlled clinical trial evaluating Makena® (hydroxyprogesterone caproate injection) in patients with a history of a prior spontaneous singleton preterm delivery. A copy of the Company's press release is furnished herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby furnishes the following exhibits:

Exhibit Number	Description
99.1	Press release entitled "AMAG Pharmaceuticals Announces Topline Results From the Prolong Trial Evaluating Makena® (hydroxyprogesterone caproate injection)" issued by AMAG Pharmaceuticals, Inc. on March 8, 2019.

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: March 8, 2019

FOR IMMEDIATE RELEASE

AMAG PHARMACEUTICALS ANNOUNCES TOPLINE RESULTS FROM THE PROLONG TRIAL EVALUATING MAKENA® (hydroxyprogesterone caproate injection)

WALTHAM, Mass. March 8, 2019 – AMAG Pharmaceuticals, Inc. (NASDAQ:AMAG) announced today topline results from PROLONG (Progestin's Role in Optimizing Neonatal Gestation), a randomized, double-blinded, placebo-controlled clinical trial evaluating Makena® in patients with a history of a prior spontaneous singleton preterm delivery. The PROLONG trial was conducted as part of an approval commitment under the Food & Drug Administration's (FDA) "Subpart H" accelerated approval process.

The PROLONG trial did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints: the incidence of preterm delivery at less than 35 weeks (Makena treated group 11.0% vs. placebo 11.5%, p=.72) and the percentage of patients who met criteria for the pre-specified neonatal morbidity and mortality composite index (Makena treated group 5.4% vs 5.2%, p=.84). The adverse event profile between the two arms was comparable. Adverse events of special interest, including miscarriage and stillbirth, were infrequent and similar between the treatment and placebo groups. The PROLONG trial enrolled approximately 1,700 pregnant women, over 75 percent of which were enrolled outside the U.S.

"After the initiation of the PROLONG trial and the approval of Makena in the U.S., Makena became the standard of care for pregnant women who have had a prior spontaneous preterm birth. This led to a reluctance by U.S. physicians to enroll their patients in a placebo-controlled clinical trial and therefore, the majority of patients in the PROLONG trial were enrolled outside of the U.S., predominantly from Eastern European countries, with very different demographics compared to the Meis trial," said Julie Krop, M.D., AMAG's Chief Medical Officer. "In light of these recent findings and the inconsistencies with prior clinical evidence, we plan to conduct additional sub-group analyses of the PROLONG data, particularly focusing on patients at the highest risk of preterm delivery and the subset of patients enrolled in the U.S. We will work closely with our publications committee to further assess the data, submit the findings to the FDA, and prepare the data for peer reviewed publication."

"As Chair of the PROLONG Publications Committee, I look forward to working closely with the clinical team to conduct additional analyses and ensure these data are properly examined through the scientific peer-review process," said Sean Blackwell, M.D., Chair of the Department of Obstetrics, Gynecology, and Reproductive Sciences at the McGovern Medical School – UTHealth at Houston and Immediate Past President of the Society for Maternal-Fetal Medicine (SMFM). "Our committee will be reviewing the trial data in detail and we will be actively involved in the analysis and interpretation of the findings. It is clear that the overall study population of PROLONG is significantly different than those who participated in the NICHD MFMU trial with respect to race, socioeconomic status, and severity of disease. Thus, we need sufficient time to thoughtfully interpret these findings in the context of the prior clinical trials."

About Makena® (hydroxyprogesterone caproate injection)

Makena is a progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. Makena was approved by the FDA in February 2011 and was granted orphan drug exclusivity through February 3, 2018. In February of 2018, AMAG introduced the prefilled Makena auto-injector containing a short, thin, non-visible needle for subcutaneous use, offering patients and providers a new administration option.

Makena has certain limitations of use. While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. **It is not intended for use in women with multiple gestations or other risk factors for preterm birth.**

A multicenter, randomized, double-blind, vehicle (placebo)-controlled clinical trial (the Meis trial), which served as the basis for the FDA's approval of Makena, demonstrated a statistically significant and clinically relevant reduction in the rate of preterm birth at 37 weeks in the Makena arm (36.3%) compared to the placebo arm (54.9 %). There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Makena should not be used in women with any of the following conditions: blood clots or other blood clotting problems, breast cancer or other hormone-sensitive cancers, or history of these conditions; unusual vaginal bleeding not related to the current pregnancy, yellowing of the skin due to liver problems during pregnancy, liver problems, including liver tumors, or uncontrolled high blood pressure. Before patients receive Makena, they should tell their healthcare provider if they have an allergy to hydroxyprogesterone caproate, castor oil, or any of the other ingredients in Makena; diabetes or prediabetes, epilepsy, migraine headaches, asthma, heart problems, kidney problems, depression, or high blood pressure.

In one clinical study, certain complications or events associated with pregnancy occurred more often in women who received Makena. These included miscarriage (pregnancy loss before 20 weeks of pregnancy), stillbirth (fetal death occurring during or after the 20th week of pregnancy), hospital admission for preterm labor, preeclampsia (high blood pressure and too much protein in the urine), gestational hypertension (high blood pressure caused by pregnancy), gestational diabetes, and oligohydramnios (low amniotic fluid levels). Makena may cause serious side effects including blood clots, allergic reactions, depression, and yellowing of the skin and the whites of the eyes. The most common side effect reported with the Makena auto-injector use (and higher than with the Makena intramuscular injection) was injection site pain.

AMAG developed the Makena auto-injector with its device partner Antares Pharma, Inc., which holds issued patents on the auto-injector device and drug-device combination, the last of which expires in 2034. AMAG also holds a U.S. patent directed to subcutaneous administration and dosing of the Makena auto-injector product, which expires in 2036.

For additional product information, including full prescribing information, please visit www.makena.com.

About AMAG
AMAG is a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs. The company does this by leveraging its development and commercial expertise to invest in and grow its pharmaceutical products across a range of therapeutic areas, including women's health. For additional company information, please visit www.amagpharma.com.

Forward-Looking Statements
This press release 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, statements regarding AMAG's beliefs about clinical trial data; beliefs about the patient-populations involved in the subject trials, including the challenges with enrollment; plans to analyze and examine data, including sub-group analyses; the anticipated submission of

findings to the FDA and preparations of the data for peer reviewed publication; and expectations that the Publications Committee will review and be actively involved in the findings 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 the FDA may limit marketing of Makena and its generic formulation based on the results of the PROLONG trial, including by withdrawing approval of Makena or imposing restrictions or requiring warnings on the label; the possibility that Makena will no longer be the standard of care in the U.S. or that healthcare providers will be reluctant to prescribe Makena in light of its efficacy as compared to placebo; the possibility that further analyses will result in the discovery of data and experiences that do not support the use of Makena as a viable treatment option or that further data could negatively impact Makena's safety profile, as well as those risks identified in AMAG'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, 2018, and subsequent filings with the SEC, which are available at the SEC'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.

AMAG Pharmaceuticals Contacts:
Investors:
Linda Lennox
908-627-3424

Media:
Sarah Connors
781-296-0722