

**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): **October 29, 2019**



AMAG PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-10865

(Commission File Number)

04-2742593

(IRS Employer Identification No.)

1100 Winter Street, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	AMAG	NASDAQ Global Select Market

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.

On October 29, 2019, AMAG Pharmaceuticals, Inc. (“AMAG”) issued a press release reporting on the outcome of the previously announced U.S. Food and Drug Administration’s Bone, Reproductive and Urologic Drugs Advisory Committee meeting held on October 29, 2019. A copy of this press release is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 29, 2019 (furnished herewith).

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: October 30, 2019



**AMAG REPORTS ON FDA ADVISORY COMMITTEE MEETING FOR
MAKENA® (HYDROXYPROGESTERONE CAPROATE INJECTION)**

*Company to Comment During Third Quarter Financial Results Conference Call on
Friday, November 1, 2019, at 8:00 a.m. ET*

WALTHAM, Mass., October 29, 2019 –AMAG Pharmaceuticals, Inc. (NASDAQ:AMAG) today announced the U.S. Food and Drug Administration’s (FDA) Bone, Reproductive and Urologic Drugs Advisory Committee met to better understand and interpret the PROLONG (Progestin’s Role in Optimizing Neonatal Gestation) confirmatory clinical trial for Makena® (hydroxyprogesterone caproate injection), a treatment approved to reduce preterm birth in pregnant women who have had a prior spontaneous preterm birth. While the committee discussed multiple questions, in a mixed vote on the key question, nine advisory committee members voted to recommend that the FDA pursue withdrawal of approval for Makena and seven committee members voted to leave the product on the market under accelerated approval and require a new confirmatory trial. Among the clinicians on the advisory committee, five of the six who practice obstetrics voted to keep Makena on the market and generate more data. AMAG agrees with several committee members who voiced concern that withdrawal of Makena would leave providers with no safe treatment options for pregnant women. The advisory committee's recommendation, while not binding, will be considered by the FDA in making its decision.

“We are disappointed with the nearly split vote on this key question and we are committed to working with the FDA to identify feasible ways to generate additional efficacy data on Makena while retaining current access to the therapy for at-risk pregnant women,” said Julie Krop, M.D., chief medical officer at AMAG. “Preterm birth is an urgent public health crisis and the implications of leaving pregnant women and providers without access to therapy that is manufactured in a safe and regulated way is profoundly troubling. For more than a decade, healthcare providers have relied on hydroxyprogesterone caproate to reduce preterm delivery in high-risk patients, which aligns with recently updated treatment recommendations of the American College of Obstetrics and Gynecology, as well as the Society of Maternal-Fetal Medicine.”

Makena’s active ingredient, 17 α hydroxyprogesterone caproate (often referred to as 17P), is the only FDA-approved treatment for pregnant women who have had a prior spontaneous preterm birth (which is a substantial risk factor for recurrent preterm birth). 17P has been recognized as the standard of care and used for more than a decade by healthcare providers to treat patients with a history of spontaneous preterm birth, which represents approximately 130,000 births a year in the United States.

The approval of Makena was based on the landmark Meis trial, conducted by the National Institute of Child Health and Human Development and the Maternal-Fetal Medicine Units Network and published in the *New England Journal of Medicine* in 2003. The PROLONG trial was later conducted as part of an FDA approval commitment. Comprised of more than 1,700 pregnant women, PROLONG represents the largest trial of any progestogen studied for preterm birth prevention and is also the largest trial of a drug treating an orphan condition. It enrolled more than 75 percent of its patients from outside of the U.S., which was necessary given the routine use of 17P as the standard of care.

AMAG will provide a corporate update and discuss the company's third quarter financial results on a conference call on November 1, 2019 at 8:00 AM ET. The live webcast can be accessed on the investor page of AMAG's website at www.amagpharma.com. The conference call can be accessed by dialing (877) 412-6083 (U.S./Canada) or (702) 495-1202 (international). Use conference ID 6261528 for both domestic and international numbers. A replay of the webcast will be available on AMAG's website approximately two hours after completion of the event and will be archived for up to 30 days.

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.**

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.

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 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 ability to identify ways to generate additional efficacy data on Makena and retain current access to the therapy for at-risk pregnant women, AMAG's plans to work with the FDA, beliefs about the size of the patient population for Makena and the belief that withdrawal of 17P would leave providers with no safe treatment options for pregnant women 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 (i) the FDA takes adverse action related to Makena, including withdrawal of the product from the market, especially given the findings and recommendation of the Advisory Committee meeting that approval of 17P be withdrawn, (ii) AMAG may

not be able to generate additional efficacy data that will be satisfactory to the FDA, or (iii) healthcare providers will no longer prescribe the Makena auto-injector product even if it were to remain commercially available; as well as those risks identified in AMAG's filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2018, its Quarterly Report on Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019 and subsequent filings with SEC, including its upcoming Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, 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® and the logo are registered trademarks of AMAG Pharmaceuticals, Inc. Makena® is a registered trademark of AMAG Pharma USA, Inc.

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