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 5, 2020**

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:

☐ 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 5, 2020, AMAG Pharmaceuticals, Inc. ("AMAG," "we" or the "Company"), issued a press release, a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

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 it 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 8.01. Other Events.

On October 5, 2020, we received from the Center for Drug Evaluation and Research ("CDER") of the Food and Drug Administration ("FDA") a proposal to withdraw marketing approval of Makena (hydroxyprogesterone caproate injection) and notice of opportunity for a hearing (the "Notice").

The Notice provides AMAG with the opportunity to request a hearing within 15 days of receipt of the Notice and invites holders of the approved generics of Makena to submit comments. If AMAG files a timely request for a hearing, we must, within 30 days of receipt of the Notice, submit data, information and analyses to demonstrate that there is a genuine and substantial issue of material fact that requires a hearing. The FDA Commissioner would decide whether to grant AMAG's request for a hearing and, if granted, would conduct such hearing and thereafter decide whether to withdraw approval of Makena.

The Makena label remains unchanged and during the pendency of this process, which the FDA has indicated in the frequently asked questions referred to in CDER's statement published on October 5, 2020 can take months if a hearing is pursued, Makena and the approved generic formulations of Makena will remain on the market until the Commissioner makes a final decision about these products. AMAG is evaluating the full range of potential options.

Forward Looking Statements

This report 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, expectations about the path forward for Makena and our interactions with the FDA, as well as our plans following receipt of the Notice, including the possibility of requesting a hearing and the timeline for the process, including that Makena will remain on the market 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, risks and uncertainties related to the path forward for Makena and our ability to successfully and timely request a hearing and compile information that might be helpful to the FDA; the possibility that our request for a hearing could be denied, or that the FDA will withdraw marketing approval for Makena even following such a hearing, the pursuit and planning of which could be costly and distracting to management; and those other 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, 2019 (as amended), its Current Reports on Form 8-K, its Quarterly Reports on Form 10-Q, including for the quarters ended March 31, 2020 and June 30, 2020, and in any 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated October 5, 2020 (furnished herewith)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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, Chief Business Officer & Corporate Secretary

Dated: October 5, 2020

FOR IMMEDIATE RELEASE

AMAG PHARMACEUTICALS PROVIDES UPDATE ON FDA'S PROPOSAL REGARDING MAKENA® (HYDROXYPROGESTERONE CAPROATE INJECTION)

- *The product remains on the market*
- *AMAG has 15 days to respond to the FDA*
- *AMAG continues to expect its recently announced tender offer and merger to close in November 2020*

WALTHAM, Mass., October 5, 2020 — AMAG Pharmaceuticals, Inc. (NASDAQ: AMAG) announced today that it received a notice from the U.S. Food and Drug Administration (FDA) that the FDA is proposing to withdraw approval of Makena® (hydroxyprogesterone caproate injection), a treatment approved to reduce preterm birth in pregnant women who have had a prior spontaneous preterm birth. The FDA in its letter also notified AMAG that the company has the opportunity to request a hearing on the withdrawal.

AMAG is evaluating its full range of potential options. The company has 15 days to respond to the FDA indicating whether AMAG would like to proceed with a hearing. If AMAG does request a hearing, the FDA Commissioner would decide whether to grant AMAG's request and, if granted, would conduct a hearing and decide whether to withdraw approval following the hearing. This process can take months and during this time Makena and the approved generics of Makena will remain on the market, according to the FDA.

"We disagree with the FDA's proposal to withdraw Makena without having the opportunity to meet with them to discuss the generation of additional effectiveness data while preserving access for patients to the only FDA approved treatment option for indicated women," said AMAG CEO Scott Myers. "We are reviewing our options, including the opportunity to request an oral hearing, and will respond to the agency within the allotted time. We continue to expect the transaction with Covis to close in November 2020."

At this time, it is important to note that Makena's approval and product label remain unchanged. The product continues to remain available to patients and prescribers. You may learn more about current medical society guidelines by visiting the American College of Obstetricians and Gynecologists and Society for Maternal-Fetal Medicine.

"I am concerned that withdrawal of Makena, as well as the generic equivalents, would leave vulnerable women with high risk pregnancies without access to a safe medication that physicians have relied upon for years, and has previously been shown to be highly effective when studied by the NICHD in a U.S. only population," Sean Blackwell M.D., Chair of the Department of Obstetrics, Gynecology, and Reproductive Sciences at the McGovern Medical School – UTHealth at Houston. "The PROLONG trial did not re-affirm efficacy, in my opinion, because it did not include enough women at high enough preterm birth risk. Given the results of the original NICHD trial, removing the ability for physicians and their patients to make a shared-decision on the benefits and risks of the only FDA-approved medication to prevent preterm birth is disappointing."

AMAG believes the totality of clinical data on Makena supports its continued positive benefit-risk profile and remains fully committed to retaining patient access to approved therapy. Makena and the generic equivalents are the only FDA-approved treatments available for pregnant women at risk for recurrent preterm birth.

Preterm birth is the leading cause of infant morbidity and mortality in the U.S, [i] and a history of spontaneous preterm birth is a substantial risk factor for recurrent preterm birth.[ii] Women, particularly those of color, are profoundly impacted by preterm birth, which is associated with the potential for babies born early to experience lifelong complications. [iii] There is also increasing recognition that health care outcomes, such as preterm birth, are impacted by social determinants of health.[iv]

ABOUT AMAG
AMAG is a commercial-stage biopharmaceutical 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. 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, expectations about the path forward for Makena and our interactions with the FDA, our plans following receipt of the Notice, including the possibility of requesting a hearing and the timeline for the process and that Makena will remain on the market, beliefs about the impact of withdrawal on the patient population and data supporting the efficacy of Makena, including our belief that the totality of clinical data on Makena supports its continued positive benefit-risk profile, and expectations for the recently announced tender offer and merger transaction 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, risks and uncertainties related to the path forward for Makena and our ability to successfully and timely request a hearing and compile information that might be helpful to the FDA; the possibility that our request for a hearing could be denied, or that the FDA will withdraw marketing approval for Makena even following such a hearing, the pursuit and planning of which could be costly and distracting to management and those other 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, 2019 (as amended), its Current Reports on Form 8-K, its Quarterly Reports on Form 10-Q, including for the quarters ended March 31, 2020 and June 30, 2020, and in any 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.

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[i] March of Dimes. Long-term Health Effects of Premature Birth. https://www.marchofdimes.org/complications/long-term-health-effects-of-premature-birth.aspx. Accessed October 22, 2019
[ii] March of Dimes. Preterm Labor and Premature Birth: Are You at Risk? https://www.marchofdimes.org/complications/preterm-labor-and-premature-birth-are-you-at-risk.aspx. Accessed October 22, 2019
[iii] National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health. Preterm Birth. https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm. Accessed October 22, 2019
[iv] Importance of social determinants of health and cultural awareness in the delivery of reproductive health care. ACOG Committee Opinion No. 729. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018;131:e43–8