AMAG PHARMACEUTICALS INC.
Form 8-K
July 11, 2014

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): **July 10, 2014**

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)

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))

Item 8.01. Other Events.

On May 8, 2014, the European Medicines Agency s (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) met to discuss the benefit-risk balance of Rienso (ferumoxytol) 30 mg/ml solution for Injection as part of a regular Periodic Safety Update Report (PSUR) review. The PSUR is a document summarizing global post-marketing adverse events and overall benefit-risk balance that is submitted to the EMA by the marketing authorization holder (the MAH) of a pharmaceutical product at intervals prescribed by regulations. As part of its assessment, which included the review of recent serious hypersensitivity reactions with Rienso, PRAC requested that Takeda Pharmaceutical Company Limited (Takeda), the MAH for Rienso in Europe, submit supplementary information to enable further assessment and discussion about Rienso. In addition, at PRAC s request, Takeda, along with AMAG Pharmaceuticals, Inc. (the Company), participated in an Oral Explanation meeting held on July 8, 2014.

On July 10, 2014, PRAC informed Takeda that PRAC has confirmed the benefits of Rienso outweigh its risks and will make the recommendation to the Committee for Medicinal Products for Human Use (CHMP) that changes should be made to the product label to better manage the risk of hypersensitivity reactions. These changes include the recommendation, among other measures, that Rienso should be administered to patients by infusion over at least 15 minutes (instead of by injection) and that it should be contraindicated in patients with any known history of drug allergy. PRAC s recommendations are subject to review by CHMP, which will discuss the recommendation of PRAC and provide its final opinion to the European Commission at the CHMP meeting currently scheduled for the week of July 21, 2014 (the July Meeting).

Rienso is also under review by the EMA for the potential expansion of its label to include all patients with iron deficiency anemia (IDA), regardless of underlying cause, through a Type II Variation. The Company believes CHMP will render an opinion on or request supplementary information for the Type II Variation in the fourth quarter of 2014.

As background, the Company licensed the rights to ferumoxytol in 2010 in certain territories outside of the U.S., including Europe, Canada and Switzerland, to Takeda. Rienso (the trade name for ferumoxytol in Europe) was approved by the EMA in Europe in 2012 for the treatment of IDA in adult patients with chronic kidney disease (CKD). Takeda has been commercializing Rienso in Europe (currently in nine countries).

By filing this report, the Company makes no admission as to the materiality of any information contained herein. The information contained in this report is intended to be considered in the context of the Company s filings with the U.S. Securities and Exchange Commission (the Commission) and other public announcements that the Company has made or will make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Commission, through press releases or through other public disclosure.

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 but not limited to statements regarding expectations as to the July Meeting, the impact of PRAC s recommendation, including the impact on the Type II Variation currently under review by the EMA and the timing of the CHMP s Type II Variation opinion or requests, 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: (1) the likelihood and timing of potential approval of Feraheme® (ferumoxytol) Injection (Feraheme) in the U.S. in the broader IDA indication in light of the complete response letter the Company received from the U.S. Food & Drug Administration (the FDA) informing the Company that its supplemental new drug application for the broader indication could not be approved in its present form and stating that the Company had not provided sufficient information to permit labeling of Feraheme for safe and effective use for the proposed broader indication (Feraheme was approved by FDA for the treatment of IDA in adult patients with CKD, and the Company has been marketing Feraheme in the U.S. since its launch in 2009), (2) the possibility that following FDA review of post-marketing safety data and/or in light of the recommendation by PRAC to CHMP, the FDA and/or CHMP will request additional technical or scientific information, new studies or reanalysis of existing data, on-label warnings, post-marketing requirements/commitments or risk evaluation and mitigation strategies in the current indication for IDA in adult patients with CKD for Feraheme/Rienso, (3) the Company s and Takeda s ability to successfully compete in the intravenous iron replacement market both in the U.S. and outside the U.S., including the EU, as a result of limitations, restrictions or warnings in Feraheme s/Rienso s current or future label, including any restrictions recommended by CHMP to the European Commission at the upcoming July Meeting, (4) Takeda s ability to obtain regulatory approval for Rienso in the EU and Feraheme in Canada in the broader IDA patient population, especially in light of the recommendation of PRAC to CHMP, (5) the possibility that significant safety or drug interaction problems reported as part of periodic safety reports with respect to Feraheme/Rienso could affect sales or the Company s ability to market the product both in the U.S. and outside of the U.S., (6) the relationship between Takeda and the Company and the impact on commercialization efforts regarding Feraheme/Rienso in the EU and Canada, (7) the possibility that the Company will disseminate future Dear Healthcare Provider letters in the U.S. (or, working with Takeda, in Europe or other markets) and (8) other risks identified in the Company s filings with the Commission, including the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 and subsequent filings with the Commission. 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.

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/ William K. Heiden
William K. Heiden
President and Chief Executive Officer

Date: July 11, 2014