AMAG PHARMACEUTICALS INC.
Form 8-K
June 03, 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): **June 3, 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.

Based on a review of global post-marketing data, AMAG Pharmaceuticals, Inc. (the Company or AMAG) has proposed changes to the current U.S. label of Feraheme® (ferumoxytol) Injection (Feraheme). Feraheme was approved by the Food and Drug Administration (the FDA) for the treatment of iron deficiency anemia (IDA) in adult patients with chronic kidney disease (CKD), and AMAG has been marketing Feraheme in the U.S. since its launch in 2009.

The intended purpose of the label changes in the U.S. is to strengthen the warnings and precautions section of the label and mitigate the risk of serious hypersensitivity reactions, including anaphylaxis, in order to enhance patient safety. The proposed changes were sent to the FDA on June 2, 2014 and are subject to review and approval by the FDA.

The Company also is working with its partner, Takeda Pharmaceutical Company Limited (Takeda), regarding changes being effected to the current label of Feraheme in Canada. The changes to the Feraheme label in Canada are expected to be finalized this month.

On May 8, 2014, the European Medicines Agency s (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) met to discuss the risk/benefit ratio of Rienso® (ferumoxytol) 30 mg/ml solution for Injection as part of a Periodic Safety Update Report (PSUR) review. The PSUR is a document summarizing global post-marketing adverse events that is submitted to the EMA by the marketing authorization holder (the MAH) of a pharmaceutical product at intervals prescribed by regulations. Rienso was approved by the EMA in Europe in 2012 for the treatment of IDA in adult patients with CKD, and Takeda has been commercializing Rienso in Europe, currently in nine European Union countries. Following a review of post-marketing data included in the most recently submitted PSUR, PRAC requested that Takeda, the MAH for Rienso in Europe, together with the Company, submit supplementary information to enable further assessment and discussion at an upcoming PRAC meeting. PRAC will then make recommendations about the risk/benefit ratio of Rienso to the Committee for Medicinal Products for Human Use (CHMP).

In agreement with PRAC, Takeda has issued a Direct Healthcare Professional Communication (DHPC) letter reminding physicians in Europe of certain risks included in the special warnings and precautions sections of the Rienso label. Hypersensitivity reactions, including anaphylaxis/anaphylactoid reactions, which can be life-threatening or fatal, have also been reported with other approved intravenous IV iron products.

Rienso is also under review by the EMA for the potential expansion of its label to include all patients with IDA, regardless of underlying cause, through a Type II Variation. Based on the timing of the ongoing PRAC review, the Company now expects that an opinion from the CHMP would likely be rendered in the third quarter of 2014.

By filing this information, the Company makes no admission as to the materiality of any information in this report. 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 makes, 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 the anticipated changes to the current labels of Feraheme in the U.S. and Canada, the dissemination of a DHPC letter in Europe, the ongoing PRAC review and the expected timing of the CHMP opinion of the potential expansion of the Rienso label to include all patients with IDA, regardless of underlying cause, 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) uncertainties regarding the likelihood and timing of potential approval of Feraheme in the U.S. in the broader iron deficiency anemia (IDA) indication in light of the complete response letter the Company received from the U.S. Food & Drug Administration (the FDA) informing AMAG 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, (2) the possibility that following FDA review of post-marketing safety data, the FDA 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, (3) the possibility that the Company will disseminate future Dear Healthcare Provider letters in the U.S. and/or in Europe, working with Takeda, (4) uncertainties regarding the Company s and Takeda s ability to successfully compete in the IV 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 that put Feraheme/Rienso at a competitive disadvantage, (5) uncertainties regarding Takeda s ability to retain marketing authorization for Rienso in the EU in light of the ongoing review by PRAC, (6) uncertainties regarding Takeda s ability to obtain regulatory approval for Rienso in the EU and Feraheme in Canada in the broader IDA patient population, (7) 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., (8) the possibility that one outcome of PRAC s safety review is a label change for Rienso in the EU (9) other risks identified in AMAG 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.

AMAG Pharmaceuticals and Feraheme are registered trademarks of AMAG Pharmaceuticals, Inc. Rienso is a trademark of Takeda Pharmaceuticals Company Limited.

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/ Scott B. Townsend

General Counsel and Senior Vice President of Legal Affairs

Date: June 3, 2014