AMAG PHARMACEUTICALS INC.
Form 8-K
January 09, 2015

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): **January 7, 2015**

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 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:

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 June 2, 2014, AMAG Pharmaceuticals, Inc. (the Company) proposed to the U.S. Food and Drug Administration (FDA) changes to the current U.S. label of Feraheme® (ferumoxytol) Injection based on a review of global post-marketing data. The intended purpose of the label changes in the U.S. was 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 subject to review and approval by the FDA.

After considering the Company s June 2014 submission and other information, on January 7, 2015, the FDA notified the Company that it believes new safety information should be included in the labeling for Feraheme, including, among other things, a boxed warning to highlight the risks of serious hypersensitivity/anaphylaxis reactions and revisions that Feraheme should only be administered through an intravenous (IV) infusion (*i.e.*, not by IV injection) and should be contraindicated for patients with any known history of drug allergy. The FDA s recommended label changes go beyond what the Company proposed in June 2014.

The Company plans to submit a response to the FDA s recommendations and will work with the FDA to finalize an updated Feraheme label.

Cautionary Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (the PSLRA) and other federal securities laws. Any statements contained herein which do not describe historical facts, including among others, statements regarding the recommended label changes and expectations about the Company s interactions with the FDA 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) demand for Feraheme and the Company s ability to successfully compete in the IV iron replacement market as a result of the FDA s recommended label changes, including the boxed warning which would provide, among other things, (i) that Feraheme be administered only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions, (ii) observation for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following infusion and (iii) that hypersensitivity reactions have occurred in patients in whom a previous Feraheme dose was tolerated; (2) the outcome and timing of the process in accordance with Section 505(o) of the Federal Food, Drug and Cosmetic Act whereby the FDA is authorized to require the Company to make safety-related label changes, including prescribed periods for submitting proposed changes to the label recommended by the FDA; (3) the impact that the FDA s recommended label changes, or such additional changes as U.S. and/or non-U.S. regulators may require in the future, will have on sales of Feraheme/Rienso (Riensotm is the trade name for ferumoxytol other than in the U.S. and Canada); (4) the impact on sales if the Company disseminates future Dear Healthcare Provider letters in the U.S., Europe or Canada; (5) the ability of the Company to invest in the development and commercialization of Feraheme/Rienso outside the U.S., and the level of commercial success of any of such efforts, given the December 2014 arrangement to terminate the Company s and Takeda Pharmaceutical Company Limited s (Takeda s) license arrangement; (6) uncertainties regarding the likelihood and timing of potential approval of Feraheme/Rienso in the U.S., the EU and Canada in the broader iron

deficiency anemia (IDA) indication in light of the complete response letter the Company received from the FDA informing the Company that its supplemental new drug application (sNDA) for the broader indication could not be approved in its present form and stating that the Company has not provided sufficient information to permit labeling of Feraheme/Rienso for safe and effective use for the proposed broader indication, and similar concerns raised by European and Canadian regulators; (7) the possibility that following review of new safety information, including (i) post-marketing safety data, including reports of serious anaphylaxis, cardiovascular events, and death, and/or (ii) in light of the label changes in Europe and Canada, and/or (iii) the re-analysis of the rate of anaphylaxis in our clinical trials, the FDA or regulators in Europe and Canada 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 (REMS) in the current CKD indication for Feraheme/Rienso, or cause Feraheme/Rienso to be withdrawn from the market, and the additional costs and expenses that will or may be incurred in connection with such activities; (8) the possibility that significant safety or drug interaction problems

could arise with respect to Feraheme/Rienso and in turn affect sales or the Company s ability to market the product both in the U.S. and outside of the U.S.; (9) the Company s patents and proprietary rights both in the U.S. and outside the U.S.; (10) maintaining the benefits associated with Makena® (hydroxyprogesterone caproate injection) orphan drug exclusivity status and the risk of an Abbreviated New Drug Application (ANDA) filing, especially (i) as to Feraheme following the FDA s draft bioequivalence recommendation for ferumoxytol published in December 2012 and (ii) as to Makena given the history of the approved drug Delalutin (the original version of 17-alpha-hydroxyprogesterone caproate) for conditions other than reducing the risk of preterm birth; (11) the Company s ability to execute on its long-term strategic plan or to realize the expected results from its long-term strategic plan; (12) the possibility that the Company will not realize expected synergies and other benefits from its acquisition of Lumara Health Inc. (Lumara), as well as the Company s ability to pursue additional business development opportunities, especially in light of the Company s being highly leveraged; (13) the impact on sales of Makena from competitive, commercial payor, government (including federal and state Medicaid reimbursement policies), physician, patient or public responses with respect to product pricing, product access and sales and marketing initiatives, as well as patient compliance; (14) the uncertainty of achieving sales of Feraheme to OB/GYN specialists for the treatment of women who suffer from IDA, even assuming FDA approval for the broader indication; (15) the number of preterm birth risk pregnancies for which Makena may be prescribed, its safety and side effects profile and acceptance of pricing; (16) the likelihood that labeling changes may be used to support product liability claims that the prior product labeling did not adequately disclose the risk of adverse events; (17) compliance with restrictive and affirmative covenants with respect to substantial indebtedness incurred to finance the acquisition of Lumara, including a requirement that the Company reduce its leverage over time; (18) the possibility that the Company will need to raise additional capital from the sale of its common stock, which will cause significant dilution to its stockholders, in order to satisfy its contractual obligations, including its debt service, milestone payments that may become payable to Lumara s stockholders, or in order to pursue business development activities; (19) the manufacture of our products, including any significant interruption in the supply of raw materials or finished product and (20) other risks identified in the Company s filings with the U.S. Securities and Exchange Commission (the SEC), including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and subsequent filings with the SEC. Any of the above risks and uncertainties could materially and adversely affect the Company s results of operations, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on the Company s stock price. Use of the term including in the two paragraphs above shall mean in each case including, but not limited to. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made.

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

Date: January 9, 2015