AMAG PHARMACEUTICALS INC.
Form 8-K
March 18, 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): **March 18, 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 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.

AMAG Pharmaceuticals, Inc. (the Company) is updating the current U.S. label of Feraheme® (ferumoxytol) Injection following discussions with the U.S. Food and Drug Administration (FDA). The updated product label, also called a package insert (PI), includes, among other things:

(i) addition of a boxed warning related to the risks of serious hypersensitivity reactions or anaphylaxis, which risks previously were described only in the *Warnings and Precautions* section;
(ii) revisions to the *Dosing and Administration* section to indicate that Feraheme should only be administered by intravenous infusion; and
(iii) modifications to the *Warnings and Precautions* section to include a statement that patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products.

In addition to the updated Feraheme PI, the FDA has also approved a Patient Package Insert, which provides patients with additional information about the product. The Company intends to communicate the label changes to healthcare providers through a Dear Healthcare Provider Letter following the FDA s review of the materials.

Forward-looking Statements

This report the materials furnished herewith contain 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 Company s plans to communicate the label changes 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 intravenous iron replacement market as a result of the updated label changes, which include, among other things, (i) the addition of a boxed warning related to the risks of serious hypersensitivity reactions or anaphylaxis, (ii) revisions to remove rapid intravenous injection and retain only intravenous infusion, and (iii) modifications to include a statement that patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products; (2) the impact on sales of Dear Healthcare Provider letters; (3) the impact on U.S. sales of Feraheme as a result of the December 2014 arrangement to terminate the license arrangement with Takeda Pharmaceutical Company Limited (Takeda) related to the development and commercialization of Feraheme outside the U.S. and our decision with Takeda to initiate withdrawal of the marketing authorization of the drug in the EU and Switzerland for commercial reasons (including if patients or health-care providers in the U.S. perceive withdrawal from other markets as being the result of safety or efficacy, rather than commercial, reasons); (4) uncertainties regarding the likelihood and timing of potential approval of Feraheme in the broader iron deficiency anemia indication; (5) the possibility that the FDA or other regulators 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 for Feraheme, and the additional costs and expenses that will or may be incurred in connection with such activities; (6) 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; and (7) other risks identified in the Company 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, 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.

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: *William K. Heiden*
William K. Heiden
Chief Executive Officer

Date: March 18, 2015