AMAG PHARMACEUTICALS INC.
Form 8-K
January 08, 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): **January 7, 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 December 21, 2012, AMAG Pharmaceuticals, Inc. (the *Company*) submitted to the U.S. Food and Drug Administration (the *FDA*) a supplemental New Drug Application (the *sNDA*) under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Feraheme® (ferumoxytol) Injection, 510 mg. The sNDA seeks approval for a broader indication for Feraheme for the treatment of iron deficiency anemia (*IDA*) in adult patients who have failed or could not tolerate oral iron. As previously disclosed, on October 15, 2013, the Company received a notification from the FDA stating that the FDA was extending the target date for a decision on the sNDA under the guidelines of the Prescription Drug User Fee Act (*PDUFA*) to January 21, 2014. This represented a three-month extension of the prior PDUFA target date and was intended to give the FDA time for a full review of additional information related to the review of the sNDA submitted by the Company in response to FDA requests.

On January 7, 2014, the Company had a discussion with the FDA regarding the status of the review of the sNDA. The FDA indicated that the sNDA is under active review; however, the FDA has not yet entered into discussions with the Company regarding proposed labeling or postmarketing requirement/commitment requests for the broader indication for Feraheme. The Company believes that it has responded to all requests to date from the FDA for additional information related to the review of the sNDA. The Company plans to continue to work with the FDA to support the completion of the review of the sNDA. Potential outcomes for the review of the sNDA include approval, a complete response letter or a further extension of the PDUFA target date.

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 ongoing review by the FDA of the sNDA for a broader patient population, the Company s expectations with regard to discussions and plans with the FDA, the anticipated timeline for proposed labeling and any postmarketing requirement/commitment requests, and expectations as to the PDUFA date 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: (1) uncertainties regarding the Company s sNDA and the Company s ability to obtain regulatory approval for Feraheme in the U.S. and Canada, and Rienso outside of the U.S. and Canada, in the broader IDA indication, (2) the Company s ability

to successfully and timely complete its clinical development programs, (3) uncertainties regarding the Company s and Takeda Pharmaceutical s ability to successfully compete in the intravenous iron replacement market both in the U.S. and outside the U.S., including the EU, (4) the possibility that significant safety or drug interaction problems could arise with respect to Feraheme/Rienso, (5) uncertainties regarding the manufacture of Feraheme/Rienso or MuGard® Mucoadhesive Oral Wound Rinse, (6) uncertainties relating to the Company s patents and proprietary rights both in the U.S. and outside the U.S., (7) the risk of an Abbreviated New Drug Application (ANDA) filing following the FDA s recently published draft bioequivalence recommendation for ferumoxytol, (8) uncertainties regarding the Company s ability to compete in the oral mucositis market in the U.S. and (9) other risks identified in the Company s filings with the U.S. Securities and Exchange Commission, including the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 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
President and Chief Executive Officer

Date: January 8, 2014