AMAG PHARMACEUTICALS INC.
Form 8-K
October 17, 2013

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): **October 15, 2013**

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 7.01 Regulation FD Disclosure

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. On October 15, 2013, the Company received a notification from the FDA (the *Notification*) stating that the FDA is 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 represents a three-month extension of the prior PDUFA target date of October 21, 2013 and is 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.

During the extension the Company plans to continue its dialogue with the FDA. Potential topics for discussions with the FDA could include, without limitation, technical and scientific information, labeling, post-marketing requirements/commitments, risk evaluation and mitigation strategies in connection with the current chronic kidney disease and the proposed IDA populations, new studies or re-analyses of existing data.

The Notification states that in accordance with PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017 the FDA plans to communicate any proposed labeling and, if necessary, any postmarketing requirement/commitment requests by December 23, 2013.

A copy of the Company s press release is furnished herewith as Exhibit 99.1.

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 approval 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 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, (2) uncertainties regarding the Company s ability to compete in the oral mucositis market in the U.S., (3) uncertainties regarding the Company s ability to successfully and timely complete our clinical development programs and obtain regulatory approval for Feraheme/Rienso in the broader IDA indication both in the U.S. and outside of the U.S., including the EU, (4) the possibility that significant safety or drug interaction problems could arise with respect to Feraheme/Rienso and in turn affect sales, regulatory approval, or the Company s ability to market the product both in the U.S. and outside of the U.S., including the EU, (5) uncertainties regarding the manufacture of Feraheme/Rienso or MuGard®, (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, and (8) other risks identified in the Company s Commission filings, including the Company s Quarterly Report on Form 10-Q for the quarter ended June 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated October 16, 2013.

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: October 16, 2013

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated October 16, 2013.