AMAG PHARMACEUTICALS INC.
Form 8-K
March 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): **February 27, 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 St. **Waltham, Massachusetts**	**02451**
(Address of principal executive offices)	(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 7.01. Regulation FD

The following information and Exhibits 99.1 and 99.2 attached hereto shall not be deemed filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

AMAG Pharmaceuticals, Inc. (the ***Company***) announced on February 27, 2014 that its Chief Executive Officer will present at the Cowen and Company 34th Annual Healthcare Conference on Monday, March 3, 2014 at 4:10 p.m. ET in Boston. A live audio webcast of the discussion will be accessible through the Investors section of the Company s website at www.amagpharma.com. Following the presentation, the webcast will be archived on the Company s website for 30 days. A copy of the Company s presentation slides, which include an updated 2014 Financial Outlook slide, is furnished herewith as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby furnishes the following exhibits:

Exhibit Number	**Description**
99.1	Press release dated February 27, 2014.
99.2	Copy of Company s presentation slides dated March 2014.

Forward-looking Statements

This report and 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 or therein which do not describe historical facts, including but not limited to statements regarding the Company s planned presentation; the Company s position and plans for accelerated growth; the Company s plans to drive revenue growth by optimizing the performance of Feraheme® (ferumoxytol) Injection; key financial metrics for 2014 and the Company s 2014 financial outlook; commercial objectives and the Company s strategic plan; the Company s plans to drive revenue growth of Feraheme in the current indication and possible plans to seek to enhance Feraheme s label and expand into new markets; commercial opportunities for Feraheme in the current indication; the possibility and next steps for U.S. label expansion for Feraheme in the broader iron deficiency anemia (***IDA***) population; the Company s plans to gain additional share of the intravenous (***IV***) iron market, if regulatory approval for the broader indication is pursued and received, and other IV iron growth opportunities; expectations for label expansion outside of the U.S. and the expected timing and magnitude of milestone payments; the Company s plans to build a profitable, multi-product specialty pharmaceutical company; the Company s expectations regarding the demand for MuGard® Mucoadhesive Oral Wound Rinse and the Company s strategies to increase MuGard s commercial success; the Company s business development goals and opportunities and the Company s statement that it is well positioned for success in 2014 and beyond 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 the Company s supplemental new drug application for Feraheme in the U.S. in the broader IDA indication, (2) the possibility that following the U.S. Food and Drug Administration s (the ***FDA s***) review of post-marketing safety data, including reports of serious anaphylaxis, cardiovascular events, and death, 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 chronic kidney disease indication for Feraheme, (3) uncertainties regarding the Company s and Takeda Pharmaceutical 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 (ferumoxytol is marketed in the EU by Takeda as Rienso), (4) uncertainties regarding Takeda s ability to obtain regulatory approval for Feraheme in Canada, and Rienso in the EU, in the broader IDA patient population, (5) 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., including the EU, (6) uncertainties regarding the manufacture of Feraheme/Rienso or MuGard, (7) uncertainties relating to the Company s patents and proprietary rights, both in the U.S. and outside of the U.S., (8) the risk of an Abbreviated New Drug Application filing following the FDA s recently published draft bioequivalence recommendation for ferumoxytol, and (9) other risks identified in the Company s Securities and Exchange Commission (the ***SEC***) filings, including the Company s Annual Report

on Form 10-K for the year ended December 31, 2013 and subsequent filings with the SEC. 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.

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

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
Scott B. Townsend
General Counsel and Senior Vice President
of Legal Affairs

Date: March 3, 2014

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated February 27, 2014.
99.2	Copy of Company s presentation slides dated March 2014.