

AMAG PHARMACEUTICALS INC.

Form 8-K

April 09, 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): **April 9, 2014**

AMAG PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-10865

(Commission File Number)

04-2742593

(IRS Employer Identification No.)

1100 Winter St.

Waltham, Massachusetts

(Address of principal executive offices)

02451

(Zip Code)

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(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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ 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 Exhibit 99.1 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.

As previously announced, the Chief Executive Officer of AMAG Pharmaceuticals, Inc. (the **Company**) will be presenting at the 13th Annual Needham Healthcare Conference on Wednesday, April 9, 2014 at 2:20 p.m. ET in New York. The Company is filing this Current Report on Form 8-K to furnish a copy of the Company's presentation slides, including an updated 2014 Financial Outlook slide, which is furnished herewith as Exhibit 99.1. The presentation slides and a live audio webcast of the presentation will be accessible through the Investors section of the Company's website at www.amagpharma.com. Following the conference, the presentation slides and webcast will be archived on the Company's website for 30 days.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby furnishes the following exhibit:

Exhibit Number	Description
99.1	Copy of Company's presentation slides dated April 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 which do not describe historical facts, including, among others, statements regarding the Company's planned presentation, its 2014 financial outlook and the intended expansion and focus of the Company's goals and product portfolio, as well as those statements identified under the caption "Forward Looking Statements" in the materials furnished herewith, 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® (ferumoxytol) Injection in the U.S. in the broader iron deficiency anemia (**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 (**REMS**) in the current chronic kidney disease (**CKD**) indication for *Feraheme*, (3) uncertainties regarding the Company's and Takeda Pharmaceutical's

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ability to successfully compete in the intravenous 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* / *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® Mucoadhesive Oral Wound Rinse, (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 (*ANDA*) filing following the FDA 's recently published draft bioequivalence recommendation for ferumoxytol, (9) uncertainties regarding the Company 's ability to compete in the oral mucositis market in the U.S. and (10) other risks identified in the Company 's Securities and Exchange Commission (the *SEC*) filings, including the Company 's Annual Report on

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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: April 9, 2014

EXHIBIT INDEX

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