AMAG PHARMACEUTICALS INC.
Form 8-K
January 13, 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 13, 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 2.02. Results of Operations and Financial Condition.

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.

On January 13, 2014, AMAG Pharmaceuticals, Inc., or the Company, issued a press release providing a business update, including preliminary fourth quarter and annual 2013 financial results. A copy of the Company s press release is furnished herewith as Exhibit 99.1.

Item 7.01. Regulation FD

The following information and Exhibit 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.

The Company will present further details on the matters noted above at the 32nd Annual J.P. Morgan Healthcare Conference in San Francisco on January 15, 2014, which will be accessible by a live audio webcast through the Company s website at www.amagpharma.com on January 15, 2014 at 8:00 a.m. Pacific Time (11:00 a.m. Eastern Time). A copy of the Company s presentation slides 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 January 13, 2014.
99.2	Copy of Company s presentation slides dated January 2014.

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 statements regarding the Company s plans for the J.P. Morgan Healthcare Conference, plans to provide 2014 financial guidance after a decision from the FDA on the *Feraheme* sNDA, expected revenues for the quarter and year ended December 31, 2013, expected gross margins for the fourth quarter of 2013, expected reductions in operating expenses as compared to fiscal year 2012, the expected year end cash position, the Company s goals and statements regarding the Company s new strategic plan, including its intention to expand its portfolio with additional commercial-stage specialty products, the market growth opportunity and demand for *Feraheme*® and Rienso , commercial opportunities for *Feraheme*, including its account base and use by hospitals, growth in *Feraheme s* current indication, the expected timing for regulatory actions, both in the U.S. and the EU, plans and strategies for MuGard® Mucoadhesive Oral Wound Rinse, the impact of business development transactions on EBITDA, expectations regarding future revenue sources, the Company s ability to optimize after-tax cash flows with business development transactions, expectations that more than 50% of our revenues will be attributable to new products by 2018, statements regarding the potential size and expansion of the U.S. IV iron market opportunity and patient population, and shifting practice patterns in the IV iron market, plans to optimize net revenue per gram, plans to drive *MuGard* growth across the oral mucositis patient population, the Company s ability to operate the business with financial discipline, identify unique in-license/acquisition candidates and leverage its balance sheet strength, the Company s plans to continue growth of net revenue per gram of *Feraheme,* the Company s 2014 goals, 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: (1) uncertainties regarding the Company s sNDA and the Company s ability to obtain regulatory approval for *Feraheme* in the broader IDA indication, both in the U.S. and outside of the U.S., including the EU (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*, (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.

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

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: January 13, 2014

EXHIBIT INDEX

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