AMAG PHARMACEUTICALS INC.
Form 8-K
January 12, 2015

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 11, 2015**

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 11, 2015, AMAG Pharmaceuticals, Inc., or the Company, issued a press release providing a business update, including preliminary unaudited fourth quarter and annual 2014 financial results and its financial outlook for 2015. 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 as well as the Company s regulatory status and its strategy and growth prospects at the 33rd Annual J.P. Morgan Healthcare Conference in San Francisco on January 14, 2015, which will be accessible by a live audio webcast through the Company s website at www.amagpharma.com on January 14, 2015 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 11, 2015.
99.2	Copy of Company s presentation slides dated January 2015.

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 the Company s plans for the J.P. Morgan Healthcare Conference 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) demand for Feraheme and the Company s ability to successfully compete in the intravenous iron replacement market as a result of the FDA s recommended label changes, including a boxed warning which would provide, among other things, (i) that Feraheme be administered only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions, (ii) observation for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following infusion and (iii) that hypersensitivity reactions have occurred in patients in whom a previous Feraheme dose was tolerated; (2) the outcome and timing of the process in accordance with Section 505(o) of the Federal Food, Drug and Cosmetic Act whereby the FDA is authorized to require the Company to make safety-related label changes, including prescribed periods for submitting proposed changes to the label recommended by the FDA; (3) the impact on sales if the Company disseminates future Dear Healthcare Provider letters; (4) the ability of the Company to invest in the development and commercialization of Feraheme/Rienso outside the U.S., and the level of commercial success of any of such efforts, given the December 2014 arrangement to terminate the

Company s and Takeda Pharmaceutical Company Limited s license arrangement; (5) uncertainties regarding the likelihood and timing of potential approval of Feraheme/Rienso in the U.S., the EU and Canada in the broader iron deficiency anemia (IDA) indication; (6) the possibility that following review of new safety information, the FDA or regulators in Europe and Canada 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/Rienso, or cause Feraheme/Rienso to be withdrawn from the market, and the additional costs and expenses that will or may be incurred in connection with such activities; (7) the possibility that significant safety or drug interaction problems could arise with respect to Feraheme/Rienso or Makena® (hydroxyprogesterone caproate injection) and in turn affect sales or the Company s ability to market such product; (8) the Company s patents and proprietary rights; (9) maintaining the benefits associated with Makena s orphan drug exclusivity status; (10) the risk of an Abbreviated New Drug Application (ANDA) filing, especially (i) as to Feraheme following the FDA s draft bioequivalence recommendation for ferumoxytol published in December 2012 and (ii) as to Makena given the history of the approved drug Delalutin (the original version of 17-alpha-hydroxyprogesterone caproate) for conditions other than reducing the risk of preterm birth; (11) the Company s ability to execute on, or to realize the expected results from, its long-term strategic plan; (12) the possibility that the Company will not realize expected synergies and other benefits from its acquisition of Lumara Health Inc. (Lumara Health), as well as the Company s ability to pursue additional business development opportunities, especially in light of the Company s being highly leveraged; (13) the impact on sales of Makena from competitive, commercial payor, government (including federal and state Medicaid reimbursement policies), physician, patient or public responses with respect to product pricing, product access and sales and marketing initiatives, as well as patient compliance and the number of preterm birth risk pregnancies for which Makena may be prescribed; (14) the likelihood that labeling changes may be used to support product liability claims that the prior product labeling did not adequately disclose the risk of adverse events; (15) compliance with restrictive and affirmative covenants with respect to substantial indebtedness incurred to finance the acquisition of Lumara Health, including a requirement that the Company reduce its leverage over time; (16) the possibility that the Company will need to raise additional capital from the sale of its common stock, which will cause significant dilution to its stockholders, in order to satisfy its contractual obligations, including its debt service, milestone payments that may become payable to Lumara Health s stockholders, or in order to pursue business development activities; (17) the availability and timing of tax net operating loss carryforwards; (18) the manufacture of the Company s products, including any significant interruption in the supply of raw materials or finished product and (19) other risks identified in the Company s filings with the U.S. Securities and Exchange Commission (the SEC), including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and subsequent filings with the SEC. Any of the above risks and uncertainties could materially and adversely affect the Company s results of operations, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on the Company s stock price. Use of the term including in the two paragraphs above shall mean in each case including, but not limited to. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made.

AMAG Pharmaceuticals® and Feraheme® are registered trademarks of AMAG Pharmaceuticals, Inc. MuGard® is a registered trademark of PlasmaTech Biopharmaceuticals, Inc. (formerly known as Access Pharmaceuticals, Inc.). Rienso is a trademark of Takeda Pharmaceutical Company Limited. Lumara Health is a trademark of Lumara Health Inc. Makena® is a registered trademark of Lumara Health Inc.

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

Date: January 12, 2015

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated January 11, 2015.
99.2	Copy of Company s presentation slides dated January 2015.