AMAG PHARMACEUTICALS INC.
Form 8-K
October 21, 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): **October 21, 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

Item 7.01. Regulation FD Disclosure

The following 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 September 29, 2014, AMAG Pharmaceuticals, Inc. (the ***Company*** or ***AMAG***) announced that it had entered into a definitive agreement to acquire the maternal health business of Lumara Health Inc. (***Lumara***). Lumara markets Makena® (hydroxyprogesterone caproate injection), a U.S. Food and Drug Administration (the ***FDA***)-approved product indicated to reduce the risk of preterm birth in women who are pregnant with one baby and who have delivered one preterm baby spontaneously in the past. Concurrently on September 29, 2014, the Company and Jefferies Finance LLC (***Jefferies***) entered into a commitment letter for the purpose of obtaining the necessary financing for the acquisition. Beginning on October 21, 2014, members of the AMAG executive team will be presenting information to Jefferies and other potential lenders.

The Company is filing this Current Report on Form 8-K to disclose that, as part of these presentations, the Company will be disclosing certain information with respect to results for the Company and Lumara covering some or all of the quarter ended September 30, 2014. In particular, for the third quarter ended September 30, 2014, unit sales of Makena were 20,421 vials, representing a growth of 14% over the quarter ended June 30, 2014.

In addition, based on the three months ended August 31, 2014 (the last month for which financial information is available), Lumara is on a run rate to achieve annualized net sales of approximately $188 million and adjusted EBITDA of approximately $107 million, and the Company is on a run rate to achieve annualized total revenue of approximately $100 million and adjusted EBITDA of approximately $20 million. The Company anticipates it will achieve combined pro forma product sales of between $65 million and $70 million for the third quarter ended September 30, 2014. The Company currently expects approximately $20 million of annual operational cost savings to be achievable after completion of the acquisition of Lumara, consisting of approximately $17 million from redundant headcount and the elimination of overhead (mostly due to the consolidation of general and administrative expenses) and $3 million relating to synergies in research and development.

Forward-looking Statements

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 annualized net sales and adjusted EBITDA, units sold, anticipated combined pro forma product sales and expected synergies 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) the possibility that closing conditions for the Lumara acquisition, including those conditions related to antitrust clearance, will not be met and that the parties will be unable to consummate the proposed transaction, (2) the chance that, despite having a commitment in place, the Company will be unable to secure financing, or financing on satisfactory terms, in amounts sufficient to consummate the transaction, (3) the possibility that if the transaction is consummated, the Company may not realize the expected benefits, synergies and opportunities anticipated in connection with the transaction, including the anticipated costs synergies of $20 million, (4) the challenges of integrating the Makena commercial team into the Company, (5) 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, (6) the impact of patient compliance on units sales, (7) the uncertainty of achieving sales of Feraheme to OB/GYN specialists for the treatment of women who suffer from iron deficiency anemia (***IDA***), even assuming approval by the FDA for the broader indication, (8) the Company may face challenges in leveraging the Company s in-office injectables commercial expertise, which could result in unforeseen expenses and disrupt business operations, (9) liabilities the Company assumes from Lumara, including Lumara s class action litigation, may be higher than expected, (10) the possibility that sales of Makena will not meet expectations as a result of current and future competition from compounded products and/or future competition from generic alternatives upon expiration of exclusivity in February 2018, (11) the impact of reimbursement policies for Makena and the resulting coverage decisions and/or impact on pricing, (12) the number of preterm birth risk pregnancies for which Makena may be

prescribed, its safety and side effects profile and acceptance of pricing, (13) in connection with the Lumara acquisition, the Company will incur a substantial amount of indebtedness and will have to comply with restrictive and affirmative debt covenants, including a requirement that the Company reduce its leverage over time, (14) the possibility that the Company will need to raise additional capital from the sale of common stock, which will cause significant dilution to the Company s stockholders, in order to satisfy the Company s contractual obligations, including the Company s debt service, milestone payments that may become payable to Lumara s stockholders or in order to pursue business development activities, (15) upon consummation of the transaction, the Company will be highly leveraged and have limited cash and cash equivalent resources which may limit its ability to take advantage of attractive business development opportunities and execute on its strategic plan, (16) the possibility that the Company s tax benefits, including those acquired upon consummation of the acquisition of Lumara, will not be available in the future, (17) the likelihood and timing of potential approval of Feraheme in the U.S. in the broader IDA indication in light of the complete response letter the Company received from the FDA informing it that the Company s supplemental new drug application for the broader indication could not be approved in its present form and stating that the Company had not provided sufficient information to permit labeling of Feraheme for safe and effective use for the proposed broader indication, (18) the possibility that following FDA review of post-marketing safety data, including reports of serious anaphylaxis, cardiovascular events, and death, and/or in light of the label changes requested by the European Medicines Agency s (the ***EMA***) Pharmacovigilance Risk Assessment Committee (***PRAC***) and confirmed by the Committee for Medicinal Products for Human Use (***CHMP***), the FDA (or other regulators) 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 indication for Feraheme for IDA in adult patients with chronic kidney disease and the additional costs and expenses that will or may be incurred in connection with such activities, (19) whether the Company s proposed label changes will be acceptable to the FDA or other regulatory authorities and what impact such changes, or such additional changes as the FDA, CHMP or other regulators may require, will have on sales of Feraheme/ Rienso (Rienso is the trade name for ferumoxytol outside of the U.S. and Canada), (20) the Company s and Takeda Pharmaceutical Company Limited s (***Takeda***) 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 s/Rienso s current or future label, including the changes recommended by PRAC and confirmed by CHMP that Rienso be administered to patients by infusion over at least 15-minutes (replacing injection) and that it be contraindicated for patients with any known history of drug allergy, (21) the Company s ability to execute on its long-term strategic plan or to realize the expected results from its long-term strategic plan, (22) Takeda s ability to obtain regulatory approval for Feraheme in Canada, and Rienso in the EU, in the broader IDA patient population, (23) 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, (24) the relationship between Takeda and the Company and the impact on commercialization efforts for Feraheme/Rienso in the EU and Canada, (25) the likelihood and timing of milestone payments, if any, in connection with the Company s licensing arrangement with Takeda, (26) the manufacture of Feraheme/Rienso or MuGard (or Makena if the acquisition of Lumara is consummated), including any significant interruption in the supply of raw materials or finished product, (27) the Company s patents and proprietary rights (including those acquired in the Lumara merger) both in the U.S. and outside the U.S., (28) the risk of an Abbreviated New Drug Application filing following the FDA s draft bioequivalence recommendation for ferumoxytol published in December 2012, (29) the possibility that the Company will disseminate future Dear Healthcare Provider letters in the U.S. (or, working Takeda, in Europe or other markets), (30) uncertainties regarding the Company s ability to compete in the oral mucositis market in the U.S. and in the women s maternal health market and (31) other risks identified in the Company s filings with the Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 and subsequent filings with the Commission. Any of the above risks and uncertainties could materially and adversely affect the Company s results of operations, profitability and cash flows, which would, in turn, have a significant and adverse impact on the Company s stock price. Use of the term including 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.

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. *MuGard* is a registered trademark of Access Pharmaceuticals, Inc. Lumara Health is a trademark of Lumara Health Inc. *Makena* is a registered trademark of Lumara Health 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 hereunto duly authorized.

AMAG PHARMACEUTICALS, INC.
By: /s/ Scott B. Townsend
Scott B. Townsend
General Counsel and Senior Vice President
of Legal Affairs

Date: October 21, 2014