AMAG PHARMACEUTICALS INC.
Form 8-K
November 12, 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): **November 12, 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)

(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 2.01 Completion of Acquisition or Disposition of Assets.

Merger Agreement

On November 12, 2014 (the ***Closing Date***), AMAG Pharmaceuticals, Inc., a Delaware corporation (the ***Company*** or ***AMAG***) completed its previously announced acquisition of Lumara Health Inc., a Delaware corporation (***Lumara***), pursuant to an Agreement and Plan of Merger (the ***Merger Agreement***) with Snowbird, Inc., a Delaware corporation (***Merger Sub***) and wholly-owned subsidiary of the Company, Lumara, and Lunar Representative, LLC, as the representative of Lumara stockholders (***Stockholders Representative***) dated September 28, 2014. Pursuant to the Merger Agreement, Merger Sub merged with and into Lumara, with Lumara continuing as the surviving entity and a wholly-owned subsidiary of the Company (the ***Merger***). Lumara is a privately-held pharmaceutical company specializing in women s health. Lumara commercializes Makena®, a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

Upon the closing of the Merger (the ***Closing***), the Company paid $600 million in cash (subject to certain adjustments related to Lumara s financial position at the time of closing, including working capital, net debt and transaction expenses adjustments as set forth in the Merger Agreement) (the ***Cash Consideration***) and 3,209,971 unregistered shares of Company common stock, par value $0.01, having a value of approximately $75 million at the time of the execution of the Merger Agreement (the ***Stock Consideration***, and together with the Cash Consideration, the ***Upfront Merger Consideration***) to the holders of Lumara common stock, stock options, and restricted stock units (collectively, the ***Lumara Security Holders***). At the Closing, $7 million of the Cash Consideration was contributed into an escrow fund to secure any Lumara Security Holders payment obligations with respect to the working capital, net debt and transaction expenses adjustments, which escrow will be released upon the final determination of the Cash Consideration. Also at the Closing, $35 million of the Cash Consideration was contributed to a separate escrow fund (the ***Indemnification Escrow***) to secure the Lumara Security Holders obligations to indemnify the Company for certain matters, including breaches of representations and warranties, covenants included in the Merger Agreement, payments made by the Company to dissenting stockholders, specified tax claims, excess parachute claims, and certain claims related to the Women s Health division of Lumara, which was divested by Lumara prior to the Closing. The portion of the Indemnification Escrow that has not been reduced by any claims by the Company and is not subject to any unresolved claims will be released to the Lumara Security Holders at the earlier of (i) March 15, 2016 and (ii) 5 days after the date on which the Company s audited financial statements for its fiscal year ending December 31, 2015 are filed with the Securities and Exchange Commission (the ***Commission***).

The Merger Agreement includes future contingent payments of up to $350 million payable by the Company to the Lumara Security Holders as follows:

- a one-time payment of $100 million within 30 days of the achievement of aggregate net sales of Makena equal to or greater than $300 million in any consecutive 12 calendar month period, commencing after the month in which the Closing occurs (the ***First Milestone Period***); plus

- a one-time payment of $100 million (the ***Second Milestone Payment***) within 30 days of the achievement of aggregate net sales of Makena equal to or greater than $400 million in any consecutive 12 calendar month period that begins with a month following the last month included in the First Milestone Period (the ***Second Milestone Period***), subject to a set-off of $50 million if the Third Milestone Payment (as defined below) has been or is required to be made prior to the time when the conditions set forth in this paragraph have been satisfied; plus

- a one-time payment of $50 million (the ***Third Milestone Payment***) within 30 days of the achievement of aggregate net sales of Makena equal to or greater than $700 million in any consecutive 24 calendar month period (which may include any period included in the First Milestone Period); provided that this payment shall not be made if the Second Milestone Payment has been or is required to be made; plus

- a one-time payment of $100 million within 30 days of the achievement of aggregate net sales of Makena equal to or greater than $500 million in any consecutive 12 calendar month period that begins with a month following the last month included in the Second Milestone Period; plus

- a one-time payment of $50 million within 30 days of the achievement of aggregate net sales of Makena equal to or greater than $200 million for each calendar year from 2015 through 2019 (regardless of whether any other contingent payments were achieved or made).

In the event that the conditions to more than one contingent payment are met in any calendar year, any portion of the total amount of contingent payment due in such calendar year in excess of $100 million shall be deferred until the next calendar year in which less than $100 million in contingent payments is due. The above description of the Merger Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Merger Agreement, a copy of which is filed as Exhibit 2.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

Also on Closing Date, in connection with the Merger, the Company entered into a Credit Agreement (the ***Credit Facility***) by and among the Company, as borrower, the financial institutions listed therein as Lenders (the ***Lenders***), and Jefferies Finance LLC, as administrative agent and collateral agent for the Lenders (the ***Agent***). The proceeds of the term loans borrowed on the Closing Date (the ***Term Loans***) will be used to finance, in part, the Cash Consideration, and to pay fees and expenses in connection with the Merger and the Credit Facility.

The Credit Facility provides for Term Loans in the aggregate principal amount of $340 million and allows for the incurrence of incremental term loans in an amount up to $40 million on the terms and subject to the conditions set forth in the Credit Facility. The Term Loans bear interest, at the Company s option, at either the Eurodollar rate plus a margin of 6.25% or the prime rate plus a margin of 5.25%. The Eurodollar rate is subject to a 1.00% floor and the prime rate is subject to a 2.00% floor. The Company must repay the term loan in installments of (i) $8,500,000 per quarter due on the last day of each quarter beginning with the quarter ending March 31, 2015 through the quarter ending December 31, 2015, and (ii) $12,750,000 per quarter due on the last day of each quarter beginning with the quarter ending March 31, 2016 through the quarter ending September 30, 2020, with the balance due in a final installment on November 12, 2020. The Term Loans mature on November 12, 2020, except that the Term Loans will mature on September 30, 2018 if (a) more than $25 million in aggregate principal amount of the Company s 2.50% Convertible Senior Notes due 2019 (the ***2019 Notes***) remain outstanding (and not converted to common stock or refinanced and replaced with debt that matures following, and has no amortization prior to, the date that is six and one half years following the Closing Date, and (b) the aggregate principal amount of all Term Loans (including all undrawn incremental commitments) is greater than $50 million on and as of such date (the ***Maturity Date***). Additionally, the Credit Facility includes an annual mandatory prepayment of the term loans from 75% of the Company s excess cash flow as measured on an annual basis, with step-downs to 50%, 25% and 0% of the Company s excess cash flow if the Company s Total Net Leverage Ratio (as defined in the Credit Facility), tested as of the last day of the Company s fiscal year, is less than or equal to 2.00 to 1.00, 1.00 to 1.00 and 0.50 to 1.00, respectively. Excess cash flow is generally defined as the Company s adjusted EBITDA less debt service costs, unfinanced capital expenditures, unfinanced acquisition expenditures, and current income taxes paid, as adjusted for changes in the Company s working capital. Additionally, the Credit Facility requires mandatory prepayment of the Term Loans from the net cash proceeds of (i) certain debt issuances and (ii) certain asset sales outside the ordinary course of business and from proceeds of property insurance and condemnation events, in each case of this clause (ii) subject to the Company s right to reinvest such proceeds in the Company s business. Any voluntary prepayment or mandatory prepayment pursuant to the preceding sentence other than in connection with a change of control shall be accompanied by a prepayment premium equal to (A) 2.0% of the principal amount of such prepayment, if such prepayment is made on or prior to the date that is twelve months after the Closing Date or (B) 1.0% of the principal amount of such prepayment, if such prepayment is made after the date that is twelve months after the Closing Date and on or prior to the date that is twenty-four months after the Closing Date.

The Credit Facility is secured by liens on substantially all the Company s assets, including a pledge of 100% of the equity interests in the Company s domestic subsidiaries and an obligation to pledge 65% of the equity interests in the Company s direct foreign subsidiaries.

The Credit Facility contains customary affirmative covenants for transactions of this type and other affirmative covenants agreed to by the parties, including, among others, the provision of annual and quarterly financial statements and compliance certificates, maintenance of property, insurance, compliance with laws and environmental matters. The Credit Facility contains customary negative covenants for transactions of this type and other negative covenants agreed to by the parties, including, among others, restrictions on the incurrence of indebtedness, granting of liens, making investments and acquisitions, paying dividends, repurchases of equity interests in the Company, entering into affiliate transactions and asset sales. The Credit Facility also provides for a number of customary events of default, including, among others, payment, bankruptcy, covenant, representation and warranty, change of control and judgment defaults.

The Credit Facility requires the Company to comply with a Total Net Leverage Ratio. The Total Net Leverage Ratio must be less than or equal to (i) 4.60 to 1.00 as of the last day of the fiscal quarter ended March 31, 2015, (ii) 4.25 to 1.00 as of the last day of the fiscal quarter ended June 30, 2015, (iii) 3.85 to 1.00 as of the last day of the fiscal quarter ended September 30, 2015, (iv) 3.40 to 1.00 as of the last day of the fiscal quarter ended December 31, 2015, (v) 2.40 to 1.00 as of the last day of the fiscal quarter ended March 31, 2016, (vi) 2.05 to 1.00 as of the last day of the fiscal quarter ended June 30, 2016, (vii) 1.85 to 1.00 as of the last day of the fiscal quarter ended September 30, 2016, (viii) 1.65 to 1.00 as of the last day of the fiscal quarter ended December 31, 2016, (ix) 1.20 to 1.00 as of the last day of the fiscal quarter ended March 31, 2017, (x) 1.10 to 1.00 as of the last day of the fiscal quarter ended June 30, 2017, and (xi) 1.00 to 1.00 as of the last day of each fiscal quarter ending thereafter through the Maturity Date. For purposes of testing the Company s Total Net Leverage Ratio, the Company is permitted to net from its outstanding total indebtedness up to $25,000,000 of its domestic unrestricted cash and cash equivalents.

All obligations under the Credit Facility are unconditionally guaranteed by substantially all of the Company s direct and indirect domestic subsidiaries. These guarantees are secured by substantially all of the present and future property and assets of the guarantors.

The above description of the Credit Facility does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Credit Facility, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

Please refer to the discussion under Item 2.01 above, which is incorporated under this Item 2.03 by reference.

Item 3.02 Unregistered Sales of Equity Securities.

Pursuant to the Merger Agreement described in Item 2.01 of this Current Report on Form 8-K, which description is incorporated herein by reference, the Company issued the Stock Consideration at the Closing to each of the Lumara Security Holders who has delivered a signed counterpart signature to the registration rights and lock-up agreement to be entered into among the Company and the Lumara Security Holders and certain required transmittal materials. The issuance of the Stock Consideration to Lumara Security Holders was not registered under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act.

Item 7.01 Regulation FD Disclosure.

On November 12, 2014, the Company issued a press release announcing the completion of the Merger and related matters. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this Item 7.01 and in Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities 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.

Item 9.01 Financial Statements and Exhibits.

(a) Financial statements of businesses acquired.

The Company intends to file the financial statements relating to the Merger described in Item 2.01 above under cover of Form 8-K/A with the Commission no later than 71 calendar days after the date this Current Report on Form 8-K was required to be filed.

(b) Pro forma financial information.

The Company intends to furnish pro forma financial information relating to the Merger described in Item 2.01 above under cover of Form 8-K/A with the Commission no later than 71 calendar days after the date this Current Report on Form 8-K was required to be filed.

(d) Exhibits.

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of September 28, 2014, by and among Lumara Health Inc., AMAG Pharmaceuticals, Inc., Snowbird, Inc., and Lunar Representative, LLC as the Stockholders Representative (incorporated herein by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K filed with the Commission on September 29, 2014)
10.1	Credit Agreement, dated as of November 12, 2014, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC*
99.1	Press Release of AMAG Pharmaceuticals, Inc. issued on November 12, 2014**

* Filed herewith.

** Furnished herewith.

Company Risk Factors and Cautionary Statements

An investment in the Company s securities involves various risks and uncertainties including, among others: (1) the possibility that the Company may not realize the expected benefits, synergies and opportunities anticipated in connection with the Merger, including anticipated costs

synergies, (2) the challenges of integrating the Lumara commercial team into AMAG, (3) 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, (4) the impact of patient compliance on unit sales, (5) the uncertainty of achieving sales of Feraheme® (ferumoxytol) to OB/GYN specialists for the treatment of women who suffer from iron deficiency anemia (***IDA***), even assuming approval by the U.S. Food and Drug Administration (***FDA***) for the broader indication, (6) the Company may face challenges in leveraging its in-office injectables commercial expertise, which could result in unforeseen expenses and disrupt business operations, (7) liabilities the Company has assumed from Lumara, including the class action litigation *In Re K-V Pharmaceutical Company Securities Litigation, Case No. 4:11CV1816 AGF*, may be higher than expected, (8) 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, (9) the impact of reimbursement policies for Makena and the resulting coverage decisions and/or impact on pricing, (10) the number of preterm birth risk pregnancies for which Makena may be prescribed, its safety and side effects profile and acceptance of pricing, (11) compliance with restrictive and affirmative covenants with respect to the Credit Facility, including a requirement that the Company reduce its leverage over time, (12) the possibility that the Company will need to raise additional capital from the sale of its common stock, which will cause significant dilution to AMAG stockholders, in order to

satisfy the Company s contractual obligations, including debt service, milestone payments that may become payable to the Lumara Security Holders, or in order to pursue business development activities, (13) the Company is highly leveraged and has limited cash and cash equivalent resources which may limit its ability to take advantage of attractive business development opportunities and execute on the Company s strategic plan, (14) the possibility that the Company s tax benefits, including those acquired in connection with the Merger, will not be available in the future, (15) the likelihood and timing of potential approval of Feraheme/Rienso (Rienso is the trade name for ferumoxytol outside of the U.S. and Canada) in the U.S., Europe and Canada in the broader IDA indication in light of the complete response letter the Company received from the FDA informing AMAG that its supplemental new drug application (sNDA) 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/Rienso for safe and effective use for the proposed broader indication and similar concerns raised by European and Canadian regulators, (16) the possibility that following 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 (EMA) Pharmacovigilance Risk Assessment Committee (***PRAC***) and confirmed by the Committee for Medicinal Products for Human Use (***CHMP***), the FDA, European or Canadian 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 (REMS) in the current indication for Feraheme/Rienso for IDA in adult patients with chronic kidney disease (***CKD***) and the additional costs and expenses that will or may be incurred in connection with such activities, (17) 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, (18) the Company s and Takeda Pharmaceutical Company Limited s (***Takeda s***) ability to successfully compete in the intravenous (IV) iron replacement market both in the U.S. and outside the U.S., including Europe and Canada, 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, (19) the Company s ability to execute on its long-term strategic plan or to realize the expected results from its long-term strategic plan, (20) Takeda s ability to obtain regulatory approval for Feraheme in Canada, and Rienso in Europe, in the broader IDA patient population, especially in light of recent developments where such regulators expressed similar concerns as raised by the FDA in its complete response letter, (21) 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 Europe and Canada, (22) the relationship between Takeda and AMAG and the impact on commercialization efforts for Feraheme/Rienso in Europe and Canada, (23) the likelihood and timing of milestone payments, if any, in connection with AMAG s licensing arrangement with Takeda, (24) the manufacture of Feraheme/Rienso, Makena or MuGard® Mucoadhesive Oral Wound Rinse, including any significant interruption in the supply of raw materials or finished product, (25) the Company s patents and proprietary rights both in the U.S. and outside the U.S., (26) the risk of an Abbreviated New Drug Application (ANDA) filing for Feraheme or Makena, especially following the FDA s draft bioequivalence recommendation for ferumoxytol published in December 2012, (27) the possibility that AMAG will disseminate future Dear Healthcare Provider letters in the U.S. (or, working with Takeda, in Europe, Canada or other markets), (28) 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 (29) other risks identified in the Company s filings with the Commission, including AMAG s Quarterly Report on Form 10-Q for the quarter ended September 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 AMAG s stock price. Use of the term including in this paragraph shall mean in each case including, but not limited to.

Further, 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 the Company s intention to file financial statement and pro forma financial information 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 those discussed in the paragraph above. 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 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.

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/ William K. Heiden
William K. Heiden
President and Chief Executive Officer

Date: November 12, 2014

EXHIBIT INDEX

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