AMAG PHARMACEUTICALS INC. Form 8-K July 29, 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): July 29, 2015

AMAG PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-10865 (Commission File Number) $\begin{array}{c} \textbf{04-2742593}\\ \text{(IRS Employer Identification}\\ \text{No.)} \end{array}$

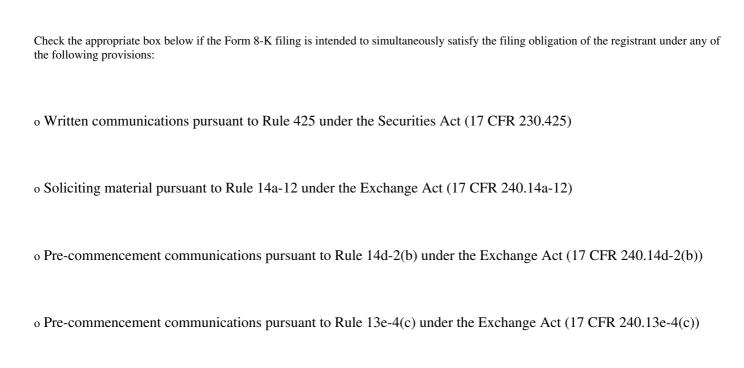
1100 Winter St. Waltham, Massachusetts (Address of principal executive offices)

02451 (Zip Code)

(617) 498-3300

(Registrant s telephone number, including area code)

(Former address, if changed since last report)



Explanatory Note

As previously disclosed in its Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2015 (the Prior 8-K), AMAG Pharmaceuticals, Inc., a Delaware corporation (the Company), entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with CBR Holdco, LLC, a Delaware limited liability company (the Seller), and CBR Acquisition Holdings Corp., a Delaware corporation (CBR), on June 29, 2015. The Stock Purchase Agreement provides that, upon the terms and subject to the conditions set forth in the Stock Purchase Agreement, the Seller agrees to sell, and the Company agrees to purchase, all of the outstanding equity securities of CBR (the Acquisition). CBR s wholly owned subsidiary, Cbr Systems, Inc. (Cbr Systems and, together with CBR, the Acquired Business), which operates as Cord Blood Registry, is a privately held provider of services for the collection, processing and long-term cryopreservation of umbilical cord blood and cord tissue stem cells for family use. Subject to the terms and conditions of the Stock Purchase Agreement, the Company has agreed to pay the Seller an aggregate of \$700.0 million in cash consideration, subject to working capital, net debt and transaction expense adjustments as set forth in the Stock Purchase Agreement. The Stock Purchase Agreement contains customary representations, warranties and covenants of the parties and contains customary conditions to closing. The above description of the Stock Purchase Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Stock Purchase Agreement, a copy of which is filed as Exhibit 2.1 to the Prior 8-K.

Item 8.01 Other Events.

The Company is filing this Current Report on Form 8-K to disclose (i) the audited financial statements of Cbr Systems (predecessor of the Acquired Business) for the period from January 1, 2012 to September 18, 2012, (ii) the audited consolidated financial statements of the Acquired Business for the period from July 13, 2012 to December 31, 2012, (iii) the audited consolidated financial statements of the Acquired Business for the years ended December 31, 2014 and December 31, 2013, (iv) the unaudited consolidated financial statements of the Acquired Business for the six months ended June 30, 2015 and June 30, 2014, (v) the unaudited condensed combined pro forma financial information of the Company as of June 30, 2015 and for the periods ended December 31, 2014 and June 30, 2015, giving effect to the Acquisition and the related financings as if they had occurred on June 30, 2015, in the case of the pro forma balance sheet as of June 30, 2015, and as of January 1, 2014, in the case of the pro forma statements of operations for the year ended December 31, 2014 and the six months ended June 30, 2015, and (vi) the Acquired Business s Management Discussion and Analysis of Financial Conditions and Results of Operations for the years ended December 31, 2014 and December 31, 2013 and for the six months ended June 30, 2015 and June 30, 2014.

As previously disclosed, on July 20, 2015, the Federal Trade Commission (the FTC) notified the Company that it is conducting an investigation into whether Lumara Health or its predecessor has engaged in unfair methods of competition with respect to *Makena* or any hydroxyprogesterone caproate product. Subsequently, the Company has gained additional insight and guidance into what information would be helpful to the FTC s investigation. The Company will fully cooperate with and will expeditiously provide a thorough response to the FTC.

The FTC noted in its letter that the existence of the investigation does not indicate that the FTC has concluded that Lumara Health or its predecessor has violated the law and the Company believes that its contracts and practices comply with relevant law and policy, including the federal Drug Quality and Security Act (the DQSA), which was enacted in November 2013, and public statements from and enforcement actions by the U.S. Food and Drug Administration (the FDA) regarding its implementation of the DQSA. The Company intends to provide the FTC a brief overview of the DQSA for context, which the Company believes will be helpful, including (i) how the statute outlined that large-scale compounding of products that are copies or near-copies of FDA-approved drugs (like *Makena*) is not in the interests of public safety, (ii) the Company s belief that the DQSA has had a significant impact on the compounding of hydroxyprogesterone caproate, and (iii) how the Company s contracts with former compounders do allow those compounders to continue to serve physicians and patients with respect to supplying medically necessary alternative/altered forms of hydroxyprogesterone caproate.

Given the early stages of this inquiry, the Company cannot at this time assess potential outcome of this investigation.

For additional information on the DQSA, please refer to the Company s Annual Report on Form 10-K under the heading *Government Regulation* - Drug Quality and Security Act in Part I, Item 1 - Business.

The information contained in this Current Report on Form 8-K, including the information contained in Exhibits 99.1, 99.2, 99.3, 99.4, 99.5 and 99.6 does not constitute an offer to sell, or the solicitation of an offer to buy, any securities and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (the PSLRA) and other federal securities laws. Any statements contained herein which do not describe historical facts, including but not limited to, statements regarding the proposed Acquisition, including the consideration to be paid and the terms and conditions thereof, and the other transactions contemplated by the Stock Purchase Agreement, expectations and beliefs regarding the FTC s investigation and the compliance with laws and policy 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. Statements about the Company s or CBR s past financial results do not, and are not meant to, predict future results. The Company can provide no assurance that such results and performance will continue. For the avoidance of doubt, any statements in this report that relate to the Acquisition are forward-looking statements within the meaning of the PSLRA and other federal securities laws.

Such risks and uncertainties include, among others, (1) the possibility that the closing conditions set forth in the Stock Purchase Agreement will not be met and that the parties will be unable to consummate the proposed Acquisition, (2) the possibility that, despite having a financing commitment in place, the Company will be unable to secure financing, or financing on satisfactory or anticipated terms, in amounts sufficient to consummate the Acquisition, (3) the possibility that, if the Acquisition is consummated, the Company may not realize the expected benefits, synergies and opportunities anticipated in connection with the Acquisition, including that the Acquisition will further diversify the Company s revenue base, be accretive to adjusted EBITDA, and result in expected annual synergies, (4) the challenges of integrating CBR into the Company s organization, including CBR s commercial team, as well as the Company s ability to retain key CBR talent and the resulting disruptions to the Company s and CBR s operations if it fails to do so, (5) the Company s ability to successfully continue the CBR business, including as a result of CBR s service based business model, the market for stem cell research and the need for strategic pricing skills to optimize the forward looking business, (6) the potential for stem cell science and its recognition, adoption and utility among the medical community, (7) the ethical, legal and social implications of stem cell research, and the possibility that negative public opinion about stem cell therapy may damage public perception of the Company s overall business and (8) such other risks identified in the Company s Securities and Exchange Commission filings, including the Company s Annual Report on Form 10-K for the year ended December 31, 2014, its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, 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 th

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
23.1	Consent of Independent Accountants (PricewaterhouseCoopers LLP).
99.1	Audited financial statements of Cbr Systems, Inc. (Predecessor Company) as of September 18, 2012 and for the period from January 1, 2012 to September 18, 2012.
99.2	Audited consolidated financial statements of CBR Holdco, LLC (Successor Company) as of December 31, 2012 and for the period from July 13, 2012 to December 31, 2012.
99.3	Audited consolidated financial statements of CBR Holdco, LLC (Successor Company) as of December 31, 2014 and 2013 and for the years ended December 31, 2014 and 2013.
99.4	Unaudited consolidated financial statements of CBR Holdco, LLC (Successor Company) as of June 30, 2015 and 2014 and for the six months ended June 30, 2015 and 2014.

CBR Holdco, LLC (Successor Company) s Management Discussion and Analysis of Financial Condition and Results of Operations for the years ended December 31, 2014 and 2013 and for the six months ended June 30, 2015 and 2014.
 Unaudited pro forma condensed combined financial information of AMAG Pharmaceuticals, Inc. as of June 30, 2015 and for the year ended December 31, 2014 and for the six months ended June 30, 2015.

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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

Chief Executive Officer

Date: July 29, 2015

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