AMAG PHARMACEUTICALS INC.
Form 8-K
January 09, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 8, 2017

AMAG Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-10865**	**04-2742593**
(State or other jurisdiction of incorporation)	(Commission file number)	(I.R.S. Employer Identification Number)

1100 Winter Street **Waltham, MA**	**02451**
(Address of principal executive offices)	(Zip code)

(617) 498-3300

(Registrant s telephone number,
including area code)

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 1.01 Entry into a Material Definitive Agreement

On January 8, 2017, AMAG Pharmaceuticals, Inc. (the Company) entered into a license agreement (the License Agreement) with Palatin Technologies, Inc. (Palatin). Under the terms of the License Agreement, subject to the conditions set forth therein, Palatin will grant to the Company (i) an exclusive license in all countries of North America (the Territory), with the right to grant sub-licenses, to research, develop and commercialize products containing bremelanotide (each a Product, and collectively, Products), an investigational product designed to be an on-demand treatment for hypoactive sexual desire disorder (HSDD) in pre-menopausal women, (ii) a non-exclusive license in the Territory, with the right to grant sub-licenses, to manufacture Products, and (iii) a non-exclusive license in all countries outside the Territory, with the right to grant sub-licenses, to research, develop and manufacture (but not commercialize) the Products.

Pursuant to the terms of the License Agreement, and subject to the conditions set forth therein, the Company is required to make the following payments to Palatin: (i) $60 million as a one-time initial research payment within five days following the date of the closing of the transactions contemplated by the License Agreement (the Effective Date), and (ii) up to an aggregate amount of $25 million to reimburse Palatin for all reasonable, documented, out-of-pocket expenses incurred by Palatin, following the Effective Date, in connection with the development and regulatory activities necessary to file a new drug application (NDA) for a Product for HSDD in the United States.

In addition, pursuant to the terms of the License Agreement, Palatin will be eligible to receive from the Company: (i) up to $80 million in specified regulatory payments upon achievement of certain regulatory milestones, and (ii) up to $300 million in sales milestone payments based on achievement of annual net sales amounts for all Products in the Territory.

The Company is also obligated to pay Palatin tiered royalties on annual net sales of Products, on a product-by-product basis, in the Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis until the latest to occur of (i) the earliest date on which there are no valid claims of Palatin patent rights covering such Product in such country, (ii) the expiration of the regulatory exclusivity period for such Product in such country and (iii) ten years following the first commercial sale of such Product in such country. Such royalties are subject to reduction in the event that: (a) the Company must license additional third party intellectual property in order to develop, manufacture or commercialize a Product or (b) generic competition occurs with respect to a Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Product in a given country, the license for such Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license.

Closing is subject to customary conditions, as well as, if required, Palatin s delivery of financial statements to be filed by the Company with the Securities and Exchange Commission (SEC) pursuant to Rule 3-05 of Regulation S-X.

The Company and Palatin have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

The License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the agreement. If any of the closing conditions have not been met within 120 days of the date of signing of the License Agreement, the Company has the right to terminate the License Agreement upon ten days written notice to Palatin. In addition, the Company has the right to terminate the License Agreement without cause, in its entirety or on a product-by-product and country-by-country basis upon at least 180 days prior written notice to Palatin. Either party may terminate the License Agreement for cause if the other party materially breaches or defaults in the performance of its obligations, and, if curable, such material breach remains uncured for 90 days.

The foregoing is only a summary of the material terms of the License Agreement and does not purport to be a complete description of the rights and obligations of the parties under such agreement. The foregoing summary is qualified in its entirety by reference to the available text of the License Agreement, a redacted copy of which the Company expects to file as an exhibit to its Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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 (the Exchange Act), 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 (the Securities Act), except as expressly set forth by specific reference in such filing.

On January 9, 2017, the Company issued a press release entitled AMAG Pharmaceuticals Provides Financial and Business Update , providing a business update, including preliminary unaudited fourth quarter and annual 2016 financial results, 2017 financial guidance, and an update on its Makena® subcutaneous auto-injector (SC) program. 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 Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, except as expressly set forth by specific reference in such filing.

The Company will present further details on the matters noted above, including the Company s License Agreement with Palatin at the 35th Annual J.P. Morgan Healthcare Conference in San Francisco on January 10, 2017, which will be accessible by a live audio webcast through the Company s website at www.amagpharma.com on January 10, 2017 at 11:30 a.m. Pacific Time (2:30 p.m. Eastern Time). A copy of the Company s presentation slides are furnished herewith as Exhibit 99.2.

Item 8.01 Other Events

On January 9, 2017, the Company issued a press release, entitled AMAG Pharmaceuticals and Palatin Technologies Enter Into Exclusive Licensing Agreement for North American Rights to Rekynda (Bremelanotide), a Potential Treatment for a Common Female Sexual Disorder , announcing that it had entered into the License Agreement. A copy of such press release is filed as Exhibit 99.3 hereto.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA) and other federal securities laws. Any statements contained herein which do not describe historical facts, including, among others, expectations for the Company s growth strategy; the Company s anticipated expansion in women s health through the licensing transaction with Palatin and plans regarding the development activity of Rekynda; the structure of planned and pending clinical trials for Rekynda; the expected timeline, indications and expenditures for clinical development and commercialization of Rekynda, including the timing for the NDA, subsequent FDA action and commercial launch; Rekynda s strategic fit for the Company s women s health business; the competitive landscape and breadth of the female sexual dysfunction (FSD) and HSDD markets and Rekynda s potential benefits and market potential; expectations for future next-generation formulations of Rekynda; the Company s and Palatin s anticipated intellectual property rights associated with Rekynda; the expected timing for the closing of the Rekynda transaction; the timing and value of payments by the Company under the Rekynda licensing transaction; the impact of the Rekynda product on the Company s financial results; expectations regarding the safety, efficacy and benefits of Rekynda, including that no boxed warning or restrictive REMS programs are anticipated; the potential value Rekynda will create for the Company s shareholders; Makena s position in the market and future growth drivers for Makena, including the potential market opportunity, progress for the next-generation development programs and customer engagement and outreach; beliefs that the current SC formulation for Makena offers potential for more convenient and alternative administration; plans to explore alternative injection sites and formulations for Makena; expected timing for the Company s supplemental new drug application (sNDA) for Makena (including expected timing for an FDA decision on the sNDA) and collection and analysis of data, and results, from the definitive pharmacokinetic study; the Company s belief that it will not request orphan drug exclusivity; the Company s intentions to request Orange Book listing of Antares eligible drug-device patents; growth drivers for Cord Blood Registry (CBR), including plans to differentiate CBR offerings and increase engagement and communications in the industry; expectations for Feraheme, including growth for the intravenous (IV) iron market and the position of Feraheme within the IV iron market; anticipated growth drivers for Feraheme, including plans to optimize net revenue per gram and grow in key segments; expected timing for reporting clinical trial results and submitting the sNDA for the expanded Feraheme label and expectations that the size of the addressable market, if the broader indication is approved, would double; preliminary and unaudited financial results and cash and debt position for 2016 and

the Company s 2017 financial guidance, including forecasted GAAP and non-GAAP revenues, GAAP and non-GAAP net income, GAAP operating income and adjusted EBITDA; expectations for the Company s key priorities in 2017, including plans to drive net product sales growth, increase non-GAAP adjusted EBITDA and undertake portfolio expansion activities, including by licensing and acquisition of products or companies; the Company s beliefs that its commercial team will serve it well for the long-term and that its record revenues in 2016 position it well for future growth in 2017; the Company s 2017 financial outlook, including revenue, operating income, adjusted EBITDA and net income; expectations regarding top-line and adjusted EBITDA growth in 2017; plans to continue to diversify the Company portfolio and achieve a mix of commercial assets and development pipeline for long-term growth; plans to continue to enhance and scale the Company s internal capabilities; and beliefs that newborn stem cells have

the potential to play a valuable role in the development of regenerative medicine 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 the closing conditions set forth in the License Agreement, including, if required, Palatin s delivery of any financial statements to be filed by the Company under Rule 3-05 of Regulation S-X, will not be met and that the parties will be unable to consummate the proposed transactions, (2) uncertainties regarding the Company s and Palatin s ability to successfully and timely complete clinical development programs and obtain regulatory approval for Rekynda in North America, (3) the possibility that significant safety or drug interaction problems could arise with respect to Rekynda, (4) the ability of the Company to raise awareness and understanding of HSDD and the potential benefits of Rekynda, (5) uncertainties regarding the manufacture of Rekynda, (6) uncertainties relating to our and Palatin s patents and proprietary rights associated with Rekynda in North America, (7) that the cost of the Rekynda transaction to the Company will be more than planned and/or will not provide the intended positive financial results, (8) that the Company or Palatin will fail to fully perform under the License Agreement, (9) uncertainty regarding the Company s ability to compete in the FSD market in North America, and (10) as well as those risks identified in the Company s filings with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2015, its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016 and subsequent filings with the SEC. Any such 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. 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 Abeona Therapeutics, Inc. Makena® is a registered trademark of AMAG Pharmaceuticals IP, Ltd. Cord Blood Registry® and CBR® are registered trademarks of CBR Systems, Inc. Rekynda™ is a trademark of Palatin.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1*	Press Release, entitled AMAG Pharmaceuticals Provides Financial and Business Update , issued by AMAG Pharmaceuticals, Inc. on January 9, 2017
99.2*	Copy of Company s presentation slides dated January 2017
99.3**	Press Release, entitled AMAG Pharmaceuticals and Palatin Technologies Enter Into Exclusive Licensing Agreement for North American Rights to Rekynda (Bremelanotide), a Potential Treatment for a Common Female Sexual Disorder , issued by AMAG Pharmaceuticals, Inc. on January 9, 2017

* Furnished herewith

** Filed herewith

SIGNATURE

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/ Joseph D. Vittiglio, Esq.
	Name:	Joseph D. Vittiglio
	Title:	Senior Vice President, General Counsel and Secretary

Date: January 9, 2017

EXHIBIT INDEX

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