AMAG PHARMACEUTICALS INC.
Form 8-K
February 03, 2017

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): **February 2, 2017**

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

As previously disclosed, on January 8, 2017 (the ***Execution Date***), AMAG Pharmaceuticals, Inc. (***AMAG***) and Palatin Technologies, Inc. (***Palatin***) entered into a licensing agreement (the ***License Agreement***) for exclusive North American rights to develop and commercialize RekyndaTM (bremelanotide), an investigational product designed for on-demand treatment of hypoactive sexual desire disorder (***HSDD***) in pre-menopausal women (the ***Licensing Transaction***). Following the satisfaction of the conditions to closing under the License Agreement, the Licensing Transaction closed on February 2, 2017 (the ***Effective Date***).

Under the terms of the License Agreement, Palatin has granted AMAG (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 (the ***Products***), (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 and subject to the conditions in the License Agreement, AMAG is required to make the following payments to Palatin: (i) $60 million as a one-time upfront payment within five days following the Effective Date (the ***Upfront Consideration***) 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 and subject to the conditions in the License Agreement, Palatin will be eligible to receive from AMAG: (i) up to $80 million in specified 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.

AMAG 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 upon 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) AMAG 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.

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

Rekynda is currently in clinical development and, pursuant to the terms of the License Agreement, Palatin will continue to conduct the clinical activities to support the NDA filing that AMAG will submit, subject to reimbursement as described above. Under the License Agreement, AMAG is assuming the obligations under manufacturing and supply agreements with Catalent Belgium S.A. AMAG is not acquiring any physical assets at closing, but may acquire remaining inventories of compounds and product from Palatin when development is completed. No

Palatin employees will be transferred to AMAG. Palatin has represented that during the fiscal-year ended June 30, 2015, the fiscal-year ended June 30, 2016, and the three-months ended September 30, 2016, Palatin spent $24.6 million, $43.1 million and $11.2 million, respectively, on research and development. Approximately 95% of the aggregate of these amounts related to bremelanotide research and development matters, including outside program costs and allocated full-time employee expenses.

The License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the License Agreement. AMAG 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 is filed with this Current Report on Form 8-K as Exhibit 10.1. AMAG has determined that the Licensing Transaction does not involve the acquisition of a business and AMAG does not believe that the amount paid (taking into account the Upfront Consideration and the value upon

closing of the additional and contingent consideration that may become payable under the License Agreement) would be deemed to exceed 10% of AMAG s total assets on a consolidated basis; however, AMAG is filing this Form 8-K to provide investors with disclosure as if Item 2.01 of Form 8-K were applicable. This filing should not be deemed an admission by AMAG that the closing of the Licensing Transaction triggers required disclosure under Item 2.01 of Form 8-K.

Risk Factors and Cautionary Statement

An investment in AMAG s securities involves various risks and uncertainties including, among others: (1) uncertainties regarding AMAG s and Palatin s ability to successfully and timely complete clinical development programs and obtain regulatory approval for Rekynda in North America, and AMAG s reliance on the contributions of Palatin for the development and regulatory activities necessary for such approval, (2) the possibility that significant safety or drug interaction problems could arise with respect to Rekynda, (3) the ability of AMAG to raise awareness and understanding of HSDD and the potential benefits of Rekynda, (4) uncertainties regarding the manufacture of Rekynda, (5) the ability of AMAG to integrate a development-stage, investigational product into its portfolio, especially given AMAG s limited experience with such products, (6) uncertainties relating to AMAG s and Palatin s patents and proprietary rights associated with Rekynda in North America, (7) the competitive landscape for Rekynda and AMAG s ability to differentiate Rekynda from other products and gain market acceptance, (8) difficulties with training and/or expanding AMAG s current sales force, (9) even if regulatory approval to market Rekynda is granted, the approval may impose limitations on the indicated use and/or require post-approval requirements, (10) the actual market size and opportunity for Rekynda may be smaller than expected, including because Rekynda is administered by subcutaneous auto-injection, which may be viewed as a disadvantage if an oral therapy is available, (11) uncertainties concerning the extent and scope of third-party reimbursement for Rekynda, (12) that the cost of the transaction to AMAG will be more than planned and/or will not provide the intended positive financial results, (13) that AMAG or Palatin will fail to comply with their respective obligations under or otherwise breach the License Agreement, (14) uncertainty regarding AMAG s ability to compete in the female sexual dysfunction market in North America, and (15) such other risks identified in AMAG s U.S. Securities and Exchange Commission (the ***Commission***) filings, 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 Commission, including its upcoming Annual Report on Form 10-K for the year ended December 31, 2016. Additional risks attendant to Rekynda identified by Palatin can be found in Palatin s filings with the Commission, including its Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2016 and subsequent filings with the Commission, including its upcoming Quarterly Report on Form 10-Q for the quarter ended December 31, 2016.

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 AMAG s beliefs regarding the present value of the Licensing Transaction, 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. AMAG cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. AMAG 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.

Item 7.01. Regulation FD.

The following information and Exhibit 99.1 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.

On February 3, 2017, the Company issued a press release, entitled AMAG Pharmaceuticals Announces Closing of Exclusive Licensing Agreement for North American Rights to RekyndaTM (Bremelanotide) , announcing that it had closed the Licensing Transaction. A copy of such press release is furnished as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

10.1 License Agreement, by and between AMAG Pharmaceuticals, Inc. and Palatin Technologies, Inc., dated January 8, 2017*+

99.1 Press Release, entitled AMAG Pharmaceuticals Announces Closing of Exclusive Licensing Agreement for North American Rights to Rekynda™ (Bremelanotide) , issued by AMAG Pharmaceuticals, Inc. on February 3, 2017++

* Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [...***...]. This exhibit has been filed separately with the Commission without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

+ Filed herewith

++ Furnished herewith

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/ Joseph D. Vittiglio
Joseph D. Vittiglio
General Counsel and Senior Vice President of Legal Affairs

Date: February 3, 2017

EXHIBIT INDEX

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