AMAG PHARMACEUTICALS INC.
Form 8-K
April 05, 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): **April 3, 2017**

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 2.01 Completion of Acquisition or Disposition of Assets.

As previously disclosed, on February 13, 2017, AMAG Pharmaceuticals, Inc. (AMAG) and Endoceutics, Inc. (Endoceutics) entered into a license agreement (the License Agreement) pursuant to which Endoceutics has granted to AMAG rights to IntrarosaTM (prasterone), an FDA-approved product for the treatment of moderate-to-severe dyspareunia (pain during sexual intercourse) (the Licensing Transaction). Following the satisfaction of the conditions to closing under the License Agreement, the Licensing Transaction closed on April 3, 2017 (the Effective Date).

Under the terms of the License Agreement, Endoceutics has granted to AMAG the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone (DHEA), including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery (the Product), excluding any dosage strengths over 13 mg per dose and combinations with other active pharmaceutical ingredients, in the United States for the treatment and prevention of vulvar and vaginal atrophy (VVA) and female sexual dysfunction (FSD) (the Field).

Subject to the terms of the License Agreement, Endoceutics has agreed to conduct clinical studies for the Product to support an application for regulatory approval for the Product for use in FSD in the United States. AMAG and Endoceutics have agreed to share the direct costs related to such studies based upon a negotiated allocation with AMAG funding up to $20.0 million. AMAG may, with Endoceutics consent (not to be unreasonably withheld, conditioned or delayed), conduct any other studies of the Product in the Field anywhere in the world for the purpose of obtaining or maintaining regulatory approval of or commercializing the Product in the Field in the United States. All data generated in connection with the above described studies would be owned by Endoceutics and licensed to AMAG pursuant to the License Agreement.

Endoceutics has granted to AMAG the exclusive right to commercialize the Product in the Field in the United States, subject to the terms of the License Agreement, including the final decision making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters. AMAG has agreed to use commercially reasonable efforts to market, promote and otherwise commercialize the Product in the Field in the United States. Endoceutics has the right to directly conduct, itself or through its affiliates or subcontractors, additional commercialization activities for the Product in the Field in the United States, which scope of activities will be agreed to by the parties acting reasonably and in good faith, and has the right to conduct activities related generally to the field of intracrinology, in each case, subject to AMAG s right to withhold approval in certain instances.

Pursuant to the terms of the License Agreement, promptly following the Effective Date, AMAG made an upfront cash payment of $50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, 300,000 of which is subject to a 180-day lock-up provision, and the other 300,000 of which is subject to a one-year lock-up provision. AMAG has also agreed to make a payment of $10.0 million to Endoceutics on the first anniversary of the Effective Date and up to $10.0 million upon the delivery of launch quantities of the Product. AMAG has also agreed to pay tiered royalties to Endoceutics equal to a percentage of net sales of the Product in the United States ranging from mid-teens (for calendar year net sales up to $150 million) to mid twenty percent (for any calendar year net sales that exceed $1 billion) (such royalty rate to be dependent on the aggregate net sales of the Product) for the commercial life of the Product, with deductions for generic competition and third party payments and after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim and (ii) ten years after the first commercial sale of the Product in the Field in the United States. Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850 million, which would be triggered at various sales thresholds.

In connection with the License Agreement, AMAG and Endoceutics entered into a manufacturing and supply agreement (the Supply Agreement) on the Effective Date, pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, has agreed to manufacture and supply the Product to AMAG and will be AMAG s exclusive supplier of the Product in the United States, subject to certain rights for AMAG to manufacture and supply the Product in the event of a cessation notice or supply failure (as such terms are defined in the Supply

Agreement). Under the Supply Agreement, Endoceutics will maintain at all times a second source supplier for the manufacture of DHEA and the drug product and identify, validate and transfer manufacturing intellectual property to the second source supplier within two years of the Effective Date. The Supply Agreement shall remain in effect until the termination of the License Agreement, unless terminated earlier by either party for an uncured material breach or insolvency of the other party, or by AMAG if it exercises its rights to manufacture and supply the Product following a cessation notice or supply failure.

Under the License Agreement, except as permitted under the License Agreement or the Supply Agreement, and except for any compounds or products affecting the melanocortin receptor pathway, including without limitation, bremelanotide (collectively, Excluded Product), AMAG is not be permitted to research, develop, manufacture, or commercialize (i) DHEA for delivery by any route of administration anywhere in world, (ii) any compound (including DHEA) or product for use in VVA anywhere in the world, or (iii) commencing on the date of an approval of the Product for the treatment of FSD in the United States and continuing for the remainder of the term of the License Agreement, any compound (including DHEA) for use in FSD (each, a Competing Product). Any compound or product for use in FSD that would be a Competing Product in the United States but that (i) does not contain DHEA and (ii) was acquired or licensed or for which the research, development, manufacture or commercialization of such compound or product is initiated by AMAG or its affiliates, in each case, prior to the date of an approval of the Product for the treatment of FSD in the United States, will be an Excluded Product and will not be subject to the exclusivity obligations under the License Agreement in the treatment of FSD, subject to certain restrictions in the License Agreement. These noncompete restrictions are subject to certain exclusions relating to the acquisition of competing programs.

AMAG and Endoceutics have made customary representations and warranties and have agreed to certain customary covenants. The License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the License Agreement. The License Agreement may be terminated by either Party for material breach that is either uncured after a 90-day notice period, or if such breach cannot be cured within such 90-day period, if the breaching party does not commence appropriate and material actions to cure such breach within the notice period and continue to diligently cure such breach for a period not to exceed 90 days, in either case, subject to tolling or determination of the arbitrators, if dispute resolution procedures are initiated within 30 days of the termination notice. AMAG has the ability to elect not to terminate the License Agreement in the case of a material breach, in which case future milestone and royalty payments owed to Endoceutics would be reduced by a negotiated percentage or by an amount determined by arbitration. Either party may terminate under certain situations relating to the bankruptcy or insolvency of the other party. AMAG may terminate the License Agreement for a valid business reason upon 365 days prior written notice to Endoceutics; or upon 60 days written notice in the event AMAG reasonably determines in good faith, after due inquiry and after discussions with Endoceutics, that AMAG cannot reasonably continue to develop or commercialize any Product as a result of a safety issue regarding the use of the Product. AMAG may also terminate the License Agreement upon 180 days notice if there is a change of control of AMAG and the acquiring entity (alone or with its affiliates) is engaged in a competing program (as defined in the Licensed Agreement) in the United States or in at least three countries within the European Union.

Endoceutics has represented that the historical research and development costs incurred to date by Endoceutics and its affiliates (including any third party costs and expenses) in connection with the Product are approximately CAD $19.6 million (approximately USD $15.0 million) since January 1, 2014, including (i) CAD $10,127,220 (approximately USD $7.7 million) during the twelve months ended December 31, 2014, (ii) CAD $4,896,520 (approximately USD $3.8 million) during the twelve months ended December 31, 2015, and (iii) CAD $4,559,816 (approximately USD $3.5 million) during the twelve months ended December 31, 2016. AMAG did not assume any liabilities (including contingent liabilities), acquire any physical assets, or hire or acquire any employees from Endoceutics in connection with the License Agreement.

The foregoing is only a summary of the material terms of the License Agreement and Supply Agreement and does not purport to be a complete description of the rights and obligations of the parties under such agreements. The foregoing summary is qualified in its entirety by reference to the available text of the License Agreement and Supply Agreement, redacted copies of which are filed with this Current Report on Form 8-K as Exhibit 10.1 and Exhibit 10.2, respectively. AMAG has determined that the Licensing Transaction does not involve the acquisition of a business and AMAG does not believe that the amount paid 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.

Forward Looking Statements

This Current Report on Form 8-K and the materials furnished herewith contain forward-looking information about AMAG within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein and therein which do not describe historical facts, including, among others, statements regarding each party s respective performance of its obligations under the License Agreement and the Supply Agreement, including with respect to funding additional clinical trials and conducting commercialization activities; anticipated clinical development plans and costs for Intrarosa to support regulatory approval of FSD; the timing and amounts of future milestone and royalty payments; and expected investment amounts by AMAG in the potential FSD label expansion and those statements in the materials furnished herewith that are designated as forward-looking statements 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 AMAG will not realize the expected benefits of the transaction, including the anticipated market opportunity and the ability of its current or expanded sales force to successfully commercialize Intrarosa; (2) the possibility that significant safety or drug interaction problems could arise with respect to Intrarosa; (3) the ability of AMAG to drive awareness of dyspareunia and the potential benefits of Intrarosa; (4) uncertainties regarding the manufacture of Intrarosa; (5) uncertainties relating to patents and proprietary rights associated with Intrarosa in the United States; (6) that the cost of the transaction to AMAG will be more than planned and/or will not provide the intended positive financial results; (7) that AMAG or Endoceutics will fail to fully perform their respective obligations under the License Agreement or the Supply Agreement; (8) uncertainty regarding AMAG s ability to compete in the dyspareunia market in the United States; and (9) other risks identified in AMAG s Securities and Exchange Commission (the Commission) filings, including its Annual Report on Form 10-K for the year ended December 31, 2016, and subsequent filings with the Commission. 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 3.02 Unregistered Sales of Equity Securities.

Pursuant to the License Agreement described in Item 2.01 of this Current Report on Form 8-K, which description is incorporated herein by reference, AMAG issued 600,000 shares of unregistered AMAG common stock to Endoceutics on April 5, 2017. The issuance of these shares to Endoceutics was not registered under the Securities Act of 1933, as amended (the Securities Act) in reliance upon an exception from registration pursuant to Regulation S promulgated under the Securities Act.

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 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.

On April 4, 2017, the Company issued a press release, entitled AMAG Pharmaceuticals Announces Closing of Exclusive Licensing Agreement with Endoceutics for U.S. Rights to IntrarosaTM (prasterone) , 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.

Exhibit Number	Description
10.1	License Agreement, by and between AMAG Pharmaceuticals, Inc. and Endoceutics, Inc., dated February 13, 2017*+
10.2	Manufacturing and Supply Agreement, by and between AMAG Pharmaceuticals, Inc. and Endoceutics, Inc., dated April 5, 2017*+
99.1	Press release entitled AMAG Pharmaceuticals Announces Closing of Exclusive Licensing Agreement with Endoceutics for U.S. Rights to IntrarosaTM (prasterone) issued by AMAG Pharmaceuticals, Inc. on April 4, 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: April 5, 2017

EXHIBIT INDEX

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