AMAG PHARMACEUTICALS INC.
Form 8-K
December 29, 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): **December 29, 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 1.01. Entry into a Material Definitive Agreement.

Item 1.02. Termination of a Material Definitive Agreement.

AMAG Pharmaceuticals, Inc. (the *Company*) and Takeda Pharmaceutical Company Limited (*Takeda*) are parties to that certain License, Development and Commercialization Agreement, dated March 31, 2010 (as amended on June 25, 2012, the *License Agreement*), pursuant to which Takeda has been commercializing Feraheme® (ferumoxytol) (under the trade name Rienso® outside of the U.S. and Canada) (the *Product* or *Feraheme/Rienso*) in Canada, the European Union (the *EU*) and Switzerland. Following a business review, Takeda has reprioritized its product portfolio and informed the Company that ferumoxytol no longer fits with Takeda s current strategy. As a result, the Company and Takeda mutually agreed to terminate the License Agreement and transition the commercialization of the Product to the Company. In connection therewith, on December 29, 2014, the Company and Takeda entered into a termination agreement detailing the terms and conditions of such termination and outlining certain transitional services that Takeda will be providing to the Company to facilitate the transition of the Product to the Company (the *Termination Agreement*). Pursuant to the Termination Agreement, the Company and Takeda have agreed to effectuate the termination of the License Agreement on a rolling basis, whereby the termination will be effective for a particular geographic territory (*e.g.*, countries under the regulatory jurisdictions of Health Canada, the European Medicines Agency (the *EMA*) and SwissMedic) upon the earlier of effectiveness of the transfer to the Company or a Withdrawal (as defined below) of the marketing authorization for such territory, with the final effective termination date to be on the third such effective date (each, a *Termination Date* and, collectively, the *Termination Dates*).

Under the License Agreement, the Company granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey in exchange for an upfront payment, certain milestone payments and tiered double-digit royalties on net product sales in certain agreed-upon territories. Under the License Agreement, except under limited circumstances, the Company retained the right to manufacture *Feraheme/Rienso* and maintained responsibility for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed-upon cost-sharing mechanism.

In connection with each Termination Date and in accordance with the terms of the Termination Agreement, Takeda is obligated, with respect to the applicable terminated territory, to transfer and assign to the Company all applicable regulatory materials and approvals and certain product data, inventory, third party contracts intellectual property rights and know-how to the Company, and to grant to the Company an exclusive license for certain Takeda technology used and applied to commercialize the Product in the applicable territory. The Termination Agreement also details the regulatory activities each party is required to perform in connection with transferring the marketing authorization from Takeda to the Company in each of the territories and the allocation of the costs of such activities. The parties agree to use commercially reasonable efforts to transfer all required activities to the Company on a territory-by-territory basis within 60 days after the applicable Termination Date (subject to a 30-day extension upon the Company s request and Takeda s consent). In addition, Takeda is obligated pursuant to the Termination Agreement to provide transition assistance to the Company, at no cost to the Company, for up to 180 days after each Termination Date for the applicable termination territory. With Takeda s consent (which shall not be unreasonably withheld or delayed), the Company may extend the transition services period for a terminated territory for a period of time reasonably necessary to complete any services that cannot be reasonably transitioned to the Company during the initial 180-day period, which extension will not exceed an additional 180 days. If the Company requests, and Takeda agrees to conduct, additional transition services after the end of the applicable transition

services period, as may be extended, the Company will reimburse Takeda s fully burdened costs for such additional services plus 5%. The Termination Agreement also provides that if the marketing authorization for the Product is suspended in a particular territory and the parties are prevented from completing the transfer of such marketing authorization to the Company within 120 days after such suspension due to applicable laws or any regulatory requirements or restrictions, or if the Company does not fulfill its obligations to initiate marketing authorization transfer by the agreed-upon, territory-specific deadline, Takeda will have the right, in Takeda s sole discretion, to withdraw such marketing authorization (a *Withdrawal*).

In consideration for the early termination of the License Agreement and the activities to be performed by the Company earlier than contemplated under the License Agreement, and in lieu of any future cost-sharing and milestone payments contemplated by the License Agreement, Takeda agreed to make certain payments to the Company, subject to certain terms and conditions, including up to approximately $6.7 million in connection with clinical study obligations, pharmacovigilance activities, regulatory filings and support, commercialization and back-office support and distribution expenditures and a $3 million milestone payment payable subject to certain regulatory conditions.

In connection with the termination, the Company expects to accelerate the recognition of $43.4 million related to the remaining deferred revenue received by the Company for upfront and milestones achieved to date which the Company expects to recognize within the next 12 months. In addition, the Company expects to recognize product sales to Takeda and the related cost of goods totaling $2.7 million and $2.4 million, respectively, that were previously deferred, within the next 12 months. The Company will assume any post-marketing obligations of Takeda as part of the Termination Agreement, including costs that otherwise would have been Takeda s obligation under the License Agreement for the ongoing pediatric studies and the initiated multi-center clinical trial to be conducted to determine the safety and efficacy of repeat doses of *Feraheme/Rienso* for the treatment of iron deficiency anemia in patients with hemodialysis dependent chronic kidney disease.

Additionally, the Supply Agreement, dated February 7, 2014, by and between the Company and Takeda Pharmaceuticals International, GMBH A/S (*GMBH*), an affiliate of Takeda (the *Supply Agreement* and, together with the License Agreement, the *Agreements*), which continues in effect until the expiration or termination of the License Agreement, will also terminate as of the respective Termination Date in the applicable geographic territory. The Supply Agreement was entered into in connection with the License Agreement and provides the terms on which the Company sells *Feraheme/Rienso* to Takeda to meet Takeda s requirements for commercial use of the product in the licensed territory. The Supply Agreement provides pricing terms and also provides that Takeda will reimburse the Company for certain capital expenditures and shall pay the Company a per-vial manufacturing fee.

There is no early termination penalty for the Company associated with the termination of the Agreements and there is no material relationship between Takeda (or GMBH) and the Company or its affiliates other than in respect of the Agreements and the Termination Agreement.

The foregoing summary of the material terms of the Agreements and the Termination Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement that was filed as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (the *SEC*) on May 6, 2010, the Amendment to the License Agreement filed as Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the SEC on June 29, 2012, the Supply Agreement that was filed as Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q filed with the SEC on May 5, 2014 and the Termination Agreement, a copy of which will be filed as an exhibit to the Company s Annual Report on Form 10-K for the year ending December 31, 2014 (or as an exhibit to an earlier filing), which are incorporated herein by reference.

Item 8.01. Other Events.

A copy of the Company s and Takeda s joint press release announcing entry into the Termination Agreement is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby files the following exhibit:

Exhibit Number	Description
99.1	Joint press release, dated December 29, 2014.

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/ Scott B. Townsend
Scott B. Townsend
General Counsel and Senior Vice President of Legal Affairs

Date: December 29, 2014

EXHIBIT INDEX

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