AMAG PHARMACEUTICALS INC.
Form 8-K
April 01, 2010

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 1, 2010**

AMAG PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

0-14732 (Commission File Number)	**04-2742593** (IRS Employer Identification No.)
100 Hayden Avenue **Lexington, Massachusetts** (Address of principal executive offices)	**02421** (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 April 1, 2010, AMAG Pharmaceuticals, Inc., or the Company, announced that it entered into a License, Development and Commercialization Agreement, or the Agreement, with Takeda Pharmaceutical Company Limited, or Takeda, with respect to the development and commercialization of its Feraheme® (ferumoxytol) Injection product in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively the Licensed Territory. Under the Agreement, the Company granted Takeda an exclusive license to develop and commercialize *Feraheme* in the Licensed Territory for all uses except as an imaging agent. The Company also granted Takeda a certain right of first negotiation in the event the Company seeks to commercialize *Feraheme* in the Licensed Territory as an imaging agent.

The Company will be responsible for conducting certain specified clinical studies supporting regulatory approval in the Licensed Territory along with certain modifications to these studies and additional studies required as a condition for approval in the Licensed Territory. In connection with such development, the Company will bear the costs of the pre-defined clinical studies and the costs of future modifications or additional studies will be allocated between the parties according to an agreed cost-sharing mechanism and cap. Takeda will have the right to assume the responsibility of clinical development in the event that the Company fails to fulfill its obligations under the Agreement in certain circumstances.

The Company will be responsible for filing and maintaining regulatory applications with the European Medicines Agency, the Swiss Agency for Therapeutic Products, and Health Canada, unless Takeda requests otherwise. Takeda will be responsible for filing regulatory applications in all other countries of the Licensed Territory and will be responsible for commercializing *Feraheme* throughout the Licensed Territory.

The Company will retain all manufacturing rights for *Feraheme*. The supply of product for the Licensed Territory will be provided under a separate supply agreement to be negotiated by Takeda and the Company in accordance with the material terms described in the Agreement. Under the supply agreement, the Company will be responsible for supplying all of Takeda s and its affiliates and sublicensees requirements of *Feraheme* for clinical and commercial use at defined pricing. Takeda will have rights to obtain *Feraheme* from a designated second source established by the Company upon the occurrence of certain events relating to the Company s material failure to supply product or certain defined insolvency events.

Under the Agreement, Takeda will pay the Company an upfront payment of $60 million. The Company is eligible to receive milestone payments totaling up to $220 million in developmental and commercial milestones. In addition, the Company is eligible to receive tiered double-digit royalties on net sales of *Feraheme* in the Licensed Territory, subject to certain reductions in the event of potential loss of patent exclusivity and entry of a generic product in that country. Neither the upfront payment nor any milestone payments will be refundable by the Company.

Takeda and the Company have agreed to certain restrictions regarding the commercialization of competitive products in the Licensed Territory subject to certain exclusions

and limitations. The Agreement also contains certain standstill limitations on the purchase by Takeda of securities of the Company.

Either party may terminate the Agreement in its entirety or with respect to specific countries, if the other party materially breaches the Agreement and the breach remains uncured for a defined cure period, and either party may terminate the Agreement in its entirety upon the bankruptcy of the other party. The Company may terminate the Agreement if Takeda challenges the validity or enforceability of any of the patents licensed to Takeda under the Agreement. Takeda may terminate the Agreement without cause, on six months written notice to the Company before the first commercial sale of *Feraheme* in the Licensed Territory, or twelve months thereafter, or on thirty days notice in certain circumstances. Unless terminated earlier, the Agreement will remain in effect until the cessation of all commercial sales of *Feraheme* in the Licensed Territory.

The Company intends to file the Agreement with the Securities and Exchange Commission in the future and will seek confidential treatment for certain material terms of the Agreement at such time. The press release dated April 1, 2010 announcing the entry into the Agreement and describing certain of its material terms is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

There are no material relationships between the Company or its affiliates and any of the parties to the Agreement, other than with respect to the Agreement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby files the following exhibit:

99.1	Press Release dated April 1, 2010

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 thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

By: /s/ Joseph L. Farmer
Joseph L. Farmer
General Counsel and Senior Vice President of Legal Affairs

Date: April 1, 2010

Exhibit Index

99.1	Press Release dated April 1, 2010