

AMAG PHARMACEUTICALS INC.

Form 8-K

July 01, 2009

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): **June 30, 2009**

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)

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(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:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On June 30, 2009, AMAG Pharmaceuticals, Inc., or the Company, announced that the U.S. Food and Drug Administration has granted marketing approval for *Feraheme* (ferumoxytol) Injection for intravenous, or IV, use, as an iron replacement therapy for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. The recommended dose of *Feraheme* is an initial 510 mg IV injection followed by a second 510 mg IV injection three to eight days later. *Feraheme* should be administered as an undiluted IV injection delivered at a rate of up to 1 mL/sec (30 mg/sec). The recommended *Feraheme* dose may be readministered to patients with persistent or recurrent iron deficiency anemia.

Feraheme is expected to be commercially available in the U.S. during the second half of July 2009. *Feraheme* will be distributed primarily through wholesalers and specialty distributors. The Company will market and sell *Feraheme* through its commercial organization consisting of approximately 150 seasoned professionals, including an 80-person specialized sales force, an experienced account management and reimbursement team, and a contract nurse team.

The press release, dated June 30, 2009, is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

In connection with the planned commercial launch of *Feraheme*, the Company and Catalent Pharma Solutions LLC, or Catalent, entered into a Commercial Packaging Services Agreement, dated May 29, 2009, or the Catalent Agreement, pursuant to which Catalent agreed to provide certain labeling, packaging and other related services to the Company in connection with the marketing and sale of *Feraheme*.

In addition, in October 2008, the Company entered into a Commercial Outsourcing Services Agreement, or the ICS Agreement, with Integrated Commercialization Services, Inc., or ICS, pursuant to which ICS is to serve as the Company's exclusive third party logistics provider to support the U.S. commercialization of *Feraheme*. The logistics services to be provided to the Company by ICS include customer services support, warehousing and inventory program support, distribution services support, contract administration and chargeback processing services, accounts receivable management and cash application services and financial management services.

The foregoing descriptions of the ICS Agreement and the Catalent Agreement contained in this Item 8.01 do not purport to be complete descriptions of the rights and obligations of the parties thereunder and are qualified in their entirety by reference to the full text of the contracts that are filed as Exhibits 10.1 and 10.2 to this Current Report on Form 8-K and incorporated herein by reference. Certain portions of these agreements have been omitted from this Current Report on Form 8-K and the versions of the agreements attached as Exhibit 10.1 and 10.2 hereto pursuant to a Confidential Treatment Request that the Company filed with the Securities and Exchange Commission at the time of filing this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby files the following exhibits:

10.1 Commercial Outsourcing Services Agreement, dated October 2008, by and between the Company and Integrated Commercialization Services, Inc. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission.)

10.2 Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and Catalent Pharma Solutions LLC. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission.)

99.1 Press Release dated June 30, 2009.

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: June 30, 2009

EXHIBIT INDEX

Exhibit Number	Description
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99.1	Press Release dated June 30, 2009.