AMAG PHARMACEUTICALS INC.
Form 8-K
February 08, 2016

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 5, 2016**

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 8.01 Other Events.

On February 5, 2016, AMAG Pharmaceuticals, Inc. (***AMAG*** or ***we***) received a Paragraph IV certification notice regarding an Abbreviated New Drug Application (an ***ANDA***) submitted to the U.S. Food and Drug Administration (the ***FDA***) by Sandoz Inc. requesting approval to engage in commercial manufacture, use and sale of Ferumoxytol Injection, 30 mg/mL, 17 mL single-use vials (the ***Generic Product***), a generic version of AMAG s FDA-approved drug Feraheme® (ferumoxytol) Injection for Intravenous Use.

The pharmaceutical composition and current FDA-approved use of ferumoxytol are covered by six U.S. patents, U.S. Patent Nos. 6,599,498; 7,553,479; 7,871,597; 8,501,158; 8,591,864; and 8,926,947, which are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. These patents expire at various dates, the longest of which runs through June 30, 2023. In the notice letter, Sandoz claims that the patents are invalid, unenforceable and/or not infringed by Sandoz s manufacture, use, sale or offer for sale of the Generic Product.

We are evaluating the notice letter and intend to vigorously enforce our intellectual property rights relating to ferumoxytol. Under the FDA s rules and regulations, we may, and plan to, initiate a patent infringement suit to defend the patents identified in the notice letter within 45 days after our receipt of the notice letter. Once such suit is commenced within this 45-day period, the FDA would be prevented from approving the ANDA until the earlier of 30 months or entry of a district court decision finding the patents invalid or not infringed.

Forward-Looking Statements

This Current Report on Form 8-K contains 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 which do not describe historical facts, including, among others, statements regarding our intentions to vigorously enforce our intellectual property rights and the possibility of initiating a patent infringement suit 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, whether we would be successful in patent infringement litigation, if initiated, and the possible introduction of generic competition for Feraheme, as well as those risks identified in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2014, our Quarterly Reports on Form 10-Q for the quarters ended June 30, 2015 and September 30, 2015 and subsequent filings with the Commission. Any of these risks and uncertainties could materially and adversely affect our results of operations, our profitability and our cash flows, which would, in turn, have a significant and adverse impact on our stock price. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim 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, except as may be required by law.

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, Esq.
Joseph D. Vittiglio, Esq.
Senior Vice President, General Counsel and Secretary

Date: February 8, 2016