AMAG PHARMACEUTICALS INC.
Form 8-K
May 21, 2013

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): **May 21, 2013**

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.)
100 Hayden Avenue **Lexington, Massachusetts**	**02421**
(Address of principal executive offices)	(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 8.01. Other Events.

AMAG Pharmaceuticals, Inc. (AMAG) has been made aware by Takeda Pharma AG, the exclusive product distributor of ferumoxytol in Switzerland, that it is recalling one specific batch of Rienso® (ferumoxytol) from the Swiss market. This decision is based on a cluster of four post-marketing adverse event reports in Switzerland concerning hypersensitivity reactions of varying severity following the administration of Rienso® from this batch. One of these cases included a report of a fatality. The batch was only distributed to and sold in Switzerland and the recall is limited to the specific batch and specifically Switzerland. Takeda Pharmaceutical Company Limited (Takeda) is also the exclusive distributor of this product in Canada and the European Union and Takeda Pharma AG is a wholly owned subsidiary of Takeda.

Rienso, like other IV irons, may cause serious hypersensitivity reactions, including anaphylactic reactions. AMAG and Takeda are investigating the specific Swiss batch of Rienso as well as gathering additional information regarding the four reported adverse events. New batches of Rienso may be introduced into the Swiss market based upon the information gathered and with the approval of Swissmedic.

By filing this information, AMAG makes no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of AMAG s filings with the Securities and Exchange Commission and other public announcements that AMAG makes, by press release or otherwise, from time to time. AMAG undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosure.

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

Date: May 21, 2013