

ANTARES PHARMA, INC.
Form 8-K
November 21, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): November 17, 2014

ANTARES PHARMA, INC.

(Exact name of registrant specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

1-32302
(Commission

File Number)

41-1350192
(I.R.S. Employer

Identification No.)

100 Princeton South, Suite 300, Ewing, NJ

(Address of principal executive offices)

08628

(Zip Code)

Registrant's telephone, including area code: (609) 359-3020

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 (*see* General Instruction A.2. below):

- “ 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))

Item 8.01. Other Events.

As previously disclosed, on February 28, 2014, Antares Pharma, Inc. (Antares) sued Medac Pharma, Inc. (Medac) and its foreign parent, medac GmbH, in the United States District Court for the District of Delaware alleging infringement. Antares is asserting four patents. On March 14, 2014, Antares filed a motion for preliminary injunction seeking to enjoin Medac from selling its methotrexate auto-pen product if and when such product is approved for sale in the United States, pending the final resolution of the litigation. Two of Antares' asserted patents were at issue in the preliminary injunction. On July 10, 2014, the District Court denied Antares' motion for preliminary injunction. Antares filed an appeal of the denial of the motion for preliminary injunction with the U.S. Court of Appeals for the Federal Circuit (the Court of Appeals), appealing the decision as to only one patent (RE44,846, the 846 patent). The 846 patent has 37 claims, and four were the subject of the appeal. On November 17, 2014, the Court of Appeals ruled that the District Court properly denied Antares' motion for preliminary injunction because Antares cannot show likelihood of success on the merits, stating that four claims of the one patent on appeal are invalid for failure to satisfy the original patent requirement of 35 U.S.C. § 251. Antares believes in the strength of its intellectual property and intends to vigorously prosecute its litigation claims. The litigation is expected to proceed to a jury trial unless settled by the parties; a trial date has not been set.

On March 7, 2014, Medac filed suit against Antares, LEO Pharma and its parent company LEO Pharma A/S (together, the LEO Entities) in the United States District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac's U.S. Patent 8,664,231 (the 231 patent) that was issued by the U.S. Patent and Trademark Office on March 4, 2014. The complaint states that the 231 patent relates to a concentration of more than 30mg/mL. Medac alleges that OTREXUP infringes the 231 patent, and demands that Antares and the LEO Entities be enjoined from making, using, selling, importing or offering OTREXUP and pay unspecified amounts of compensatory damages, treble damages and attorneys' fees. On November 18, 2014, Medac filed a motion for preliminary injunction seeking to enjoin Antares and the LEO Entities from selling OTREXUP in the United States, pending the final resolution of the litigation. The Company intends to defend itself vigorously.

SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This filing contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements made with respect to the strength of the Company's intellectual property and expectations with respect to litigation, and other statements regarding matters that are not historical facts, and involve predictions. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance, achievements or prospects to be materially different from any future results, performance, achievements or prospects expressed in or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terminology such as may , will , should , would , expect , intend , plan , anticipate , believe , estimate , predict , potential , seem , seek , future , continue , or a these terms or similar expressions, although not all forward-looking statements contain these identifying words. Such forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those anticipated by the forward-looking statements. Additional information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the Risk Factors section of the Company's Annual Report on Form 10-K for the year ended December 31, 2013, and in the Company's other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this report, except as 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.

ANTARES PHARMA, INC.

Date: November 21, 2014

By: /s/ Jennifer Evans Stacey

Name: Jennifer Evans Stacey, Esq.

Title:

Senior Vice President, General Counsel,

Human Resources & Secretary