ANTARES PHARMA, INC.
Form 8-K
October 12, 2017

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): October 11, 2017

ANTARES PHARMA, INC.

(Exact name of registrant specified in its charter)

Delaware	1-32302	41-1350192
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
100 Princeton South, Suite 300, Ewing, NJ		08628
(Address of principal executive offices)		(Zip Code)

(609) 359-3020

(Registrant’s telephone number, including area code)

Not Applicable

(Former name or 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 (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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On December 20, 2016, Antares Pharma, Inc. (the "Company" or "we") submitted to the U.S. Food and Drug Administration (the "FDA") a New Drug Application (the "NDA") under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for XYOSTED™ (testosterone enanthate) injection for testosterone replacement therapy. On February 24, 2017, the Company received a letter from the FDA notifying the Company that the FDA assigned a Prescription Drug User Fee Act ("PDUFA") target date for completion of its review by October 20, 2017. On September 22, 2017, the Company received FDA labeling comments with regard to the NDA and responded to the comments on September 29, 2017.

On October 11, 2017, the Company received a letter from the FDA (the "Letter") stating that, as part of its ongoing review of the NDA, the FDA has identified deficiencies that preclude the continuation of the discussion of labeling and postmarketing requirements/commitments at this time. The letter does not specify the deficiencies identified by the FDA and there has been no further clarification of the deficiencies by the FDA at this time. The Company anticipates receiving further clarification from the FDA on or before the PDUFA date. The Company intends to work with the FDA to understand the nature of the deficiencies once identified and resolve them as quickly as possible.

On October 12, 2017, the Company issued a press release (the "Press Release") announcing its receipt of the Letter. Copies of the Press Release and the Letter are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

By filing this Current Report on Form 8-K, the Company makes no admission as to the materiality of any information contained herein. The information contained in this report is intended to be considered in the context of the Company's filings with the U.S. Securities and Exchange Commission (the "Commission") and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, except as required by law, although it may do so from time to time as it believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Commission, through press releases or through other public disclosure.

This report contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, the statements regarding the Company's expectations with regard to the timing of receipt of further clarification from the FDA and the Company's expectations to work with the FDA to understand the nature of the deficiencies and resolve such deficiencies. Forward-looking statements are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Forward-looking statements are based on assumptions that we have made in light of our industry experience as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this report, you should understand that these statements are not guarantees of performance results. Forward-looking statements involve known and unknown risks, uncertainties and assumptions, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a

combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including, without limitation, the Company's ability to resolve the deficiencies once identified by the FDA in the Company's XYOSTED™ NDA, the timeframe associated with such resolution, whether any such response will be accepted by the FDA, whether FDA approval is received for XYOSTED™, for the Company's other products candidates or for its partners product candidates, delays in product introduction and marketing or interruptions in supply, a decrease in business from our major customers and partners, our inability to compete successfully against new and existing competitors or to leverage our research and development capabilities and our marketing capabilities, our inability to effectively market our products and services or obtain and maintain arrangements with our customers, partners and manufacturers, our inability to obtain adequate third-party payor coverage of our marketed products, our inability to effectively protect our intellectual property, costs associated with future litigation and the outcome of such litigation, our inability to attract and retain key personnel, changes or delays in the regulatory process, adverse economic and political conditions; and our ability to obtain additional financing, reduce expenses or generate funds when necessary. In addition, you should refer to the "Risk Factors" sections of this report and of our Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of other factors that may cause our actual results to differ materially from those described by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained in this report will prove to be accurate and, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. We encourage readers of this report to understand forward-looking statements to be strategic objectives rather than absolute targets of future performance. Forward-looking statements speak only as of the date they are made. We do not intend to update publicly any forward-looking statements to reflect circumstances or events that occur after the date the forward-looking statements are made or to reflect the occurrence of unanticipated events except as required by law. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, if at all.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Antares Pharma, Inc. dated October 12, 2017
99.2	FDA Letter received October 11, 2017

Exhibit Index

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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: October 12, 2017 By: /s/ Peter J. Graham
Name: Peter J. Graham
Title: Senior Vice President,

General Counsel, Chief Compliance Officer,

Human Resources and Secretary