

Edgar Filing: Adamas Pharmaceuticals Inc - Form 8-K

Adamas Pharmaceuticals Inc
Form 8-K
March 13, 2018

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): March 13, 2018

ADAMAS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware 001-36399 42-1560076
(State or other jurisdiction (Commission File Number) (IRS Employer Identification No.)
of incorporation)
1900 Powell Street, Suite 750 94608
Emeryville, CA
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: (510) 450-3500

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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))

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 March 13, 2018, the U.S. Food and Drug Administration's ("FDA") New Paragraph IV Certifications list was updated to reflect that an abbreviated new drug application ("ANDA") seeking authorization from the FDA to manufacture, use, or sell a generic version of GOCOVRI™ (amantadine) extended release capsules, containing one or more certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), was submitted to the FDA on January 16, 2018, and has been accepted for filing.

GOCOVRI is protected from entry of generic versions by orphan drug exclusivity until August 2024, and a portfolio of patents and patent applications until 2034. Thirteen issued patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) for GOCOVRI. Adamas intends to vigorously enforce its intellectual property rights with respect to GOCOVRI.

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.

Adamas Pharmaceuticals, Inc.

Dated: March 13, 2018 By: /s/ Jennifer J. Rhodes
Jennifer J. Rhodes
Chief Business Officer and General Counsel