

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 8-K

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.

On March 3, 2014, Titan Pharmaceuticals, Inc. (the “Company” or “Titan”) announced that the Company and its partner, Braeburn Pharmaceuticals, have agreed in principle with the U.S Food and Drug Administration (“FDA”) on the path forward for a clinical study in support of the New Drug Application for Probuphine®, Titan’s investigational subdermal implant for the maintenance treatment of opioid dependence. The proposed clinical study will be a randomized, double blind and double dummy design that will provide information for a non-inferiority comparison of a six-month treatment with a dose of four Probuphine implants to treatment with 8mg or less of an approved daily dosed sublingual formulation of buprenorphine. Details of the study, including size and the data analysis plan, will be established following the FDA’s review of a complete study protocol, which is expected to be submitted by Braeburn within the next two weeks

A copy of the press release issued by the Company is attached hereto as Exhibit 99.1 and is incorporated herein by reference,

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press Release, dated March 3, 2014.

SIGNATURE

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.

TITAN
Dated: March 4, 2014 PHARMACEUTICALS,
INC.

By: /s/ Sunil Bhonsle
Name: Sunil Bhonsle
Title: President

Exhibit Index

Exhibit No. Description

99.1 Press Release, dated March 3, 2014.