TITAN PHARMACEUTICALS INC
Form 8-K
May 01, 2013

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 1934

Date of Report (Date of earliest event reported): April 30, 2013

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

Delaware	**0-27436**	**94-3171940**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

400 Oyster Point Blvd., Suite 505, South San Francisco, CA **94080**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant s telephone number, including area code: 650-244-4990

(Former Name or Former Address, is Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of 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(b) under the Exchange Act (17 CFR 240.14a-12(b))

¨ 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.

FDA Action

On April 30, 2013, Titan Pharmaceuticals, Inc. (Titan or the Company) announced that the U.S. Food and Drug Administration has issued a Complete Response Letter (CRL) with respect to the Company s New Drug Application for Probuphine® for the maintenance treatment of adult patients with opioid dependence.

The CRL states that the FDA cannot approve the application in its present form. The FDA has requested additional data supporting the efficacy of Probuphine, including:

- The ability of Probuphine to provide opioid blockade of relevant doses of agonists
- The effect of higher doses of Probuphine, ideally doses more closely approximating the blood plasma levels associated with sublingual doses of buprenorphine of 12 to 16 mg / day
- Human factors testing of the training associated with Probuphine s insertion and removal

The CRL also included recommendations regarding product labeling and the implementation of the Risk Evaluation and Mitigation Strategy (REMS).

The press release dated April 30, 2013 is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated herein by reference.

Director Resignation

Hubert Huckel, a member of Titan s board of directors since 1995, notified the Company that he was resigning from his board position effective May 1, 2013 for personal reasons.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated April 30, 2013.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

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

Dated: May 1, 2013

Exhibit Index

Exhibit No.	Description
99.1	Press release dated April 30, 2013.