

Insys Therapeutics, Inc.
Form 8-K
October 16, 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): October 15, 2014

Insys Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35902	51-0327886
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

1333 S. Spectrum Blvd, Suite 100

Chandler, Arizona 85286

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (602) 910-2617

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 October 15, 2014, Insys Therapeutics, Inc. provided an update related to its Dronabinol Oral Solution New Drug Application. The Company announced that it received a Refusal to File Letter from the United States Food and Drug Administration (FDA) for its proprietary Dronabinol Oral Solution. The letter indicates that the FDA refused to file the NDA because it contained an inadequate or incomplete pediatric study plan. The Company is currently working with the FDA to resubmit the application as quickly as possible. A news release related to the update is filed as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d)Exhibits

Exhibit

Description

No.	Description
99.1	News release issued by Insys Therapeutics, Inc., dated October 15, 2014, entitled "Insys Provides Update on Dronabinol Oral Solution New Drug Application."

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.

Date: October 15, 2014 Insys Therapeutics, Inc.

By: /s/ Darryl S. Baker
Darryl S. Baker
Chief Financial Officer

EXHIBIT INDEX

Exhibit

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