

Onconova Therapeutics, Inc.
Form 8-K
December 04, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): **December 3, 2015**

Onconova Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

001-36020
(Commission
File Number)

22-3627252
(I.R.S. Employer
Identification No.)

375 Pheasant Run

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Newtown, PA 18940

(267) 759-3680

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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:

- ☐ 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 (17CFR 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 December 3, 2015, Onconova Therapeutics, Inc. (the "Company") received notification from the U.S. Food and Drug Administration ("FDA") that a full clinical hold has been placed on the investigational new drug application for briciclib, one of the Company's secondary clinical-stage product candidates, following a drug product lot testing failure due to visible particulates. The Company will be required to undertake appropriate remedial actions prior to re-initiating the clinical trial. The Company previously reported that enrollment in the next cohort of a Phase 1 clinical trial of briciclib was expected to resume upon completion of quality control testing of the drug product.

The Company's current efforts are focused on its lead product candidate, rigosertib. The FDA action does not affect the Company's plans with respect to the Phase 3 clinical trial of rigosertib IV in patients with higher-risk myelodysplastic syndromes (MDS) or any other rigosertib clinical trials.

SIGNATURE

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

Dated: December 4, 2015

Onconova Therapeutics, Inc.

By: /s/ Ajay Bansal
Name: Ajay Bansal
Title: Chief Financial Officer