

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**

Edgar Filing: Onconova Therapeutics, Inc. - Form 8-K

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