Onconova Therapeutics, Inc.
Form 8-K
March 09, 2016

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): **March 3, 2016**

Onconova Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-36020**	**22-3627252**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

375 Pheasant Run
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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.02. **Termination of a Material Definitive Agreement.**

On March 3, 2016, Onconova Therapeutics, Inc. (the Company) received a notice from Baxalta US Inc. (Baxalta) notifying the Company of Baxalta s election to terminate the Development and License Agreement (the Agreement), dated September 19, 2012, by and between the Company and Baxalta (as successor to Baxter Healthcare SA) for convenience, effective August 30, 2016.

The Company is currently evaluating the intravenous formulation of its lead product candidate, rigosertib, in a randomized, controlled Phase 3 clinical trial in a population of patients with higher-risk myelodysplastic syndromes (HR-MDS) who have failed hypomethylating agent therapy. The trial, referred to as INSPIRE, is designed to enroll approximately 225 patients at more than 100 sites globally. The primary endpoint of INSPIRE is overall survival, and an interim futility analysis is anticipated. Under the terms of the Agreement, Baxalta is making cost-sharing payments to the Company equal to fifty percent of the costs of the INSPIRE trial, up to $15.0 million in cost-sharing payments.

The Agreement granted Baxalta an exclusive, royalty-bearing license for the research, development and commercialization of the Company s lead product candidate, rigosertib, in all therapeutic indications in specified countries comprising most of Europe. Under the Agreement, the Company received an upfront license fee upon signing, and would have received certain pre- and post-commercialization payments and royalties if specified development and regulatory milestones had been achieved and Baxalta had engaged in sales of rigosertib in its territory. In accordance with the terms of the Agreement, upon termination, the rights that the Company had licensed to Baxalta will revert to the Company at no cost to the Company. Additionally, prior to the effective date of the termination, Baxalta will transition material to the Company and will continue to fund its share of the costs of the INSPIRE trial. The foregoing description of the Agreement is subject to, and qualified in its entirety by, the text of the Agreement, which is attached as Exhibit 10.1 to pre-effective amendment no. 2 to the Company s registration statement on Form S-1, which amendment was filed with the Securities and Exchange Commission on July 24, 2013.

Based on a Schedule 13G/A filed by Baxalta GmbH and Baxalta Incorporated on February 29, 2016, Baxalta is the beneficial owner of 2,603,295 shares of our common stock, or approximately 9.5 percent of shares outstanding based on 27,401,035 shares outstanding as of January 11, 2016.

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: March 9, 2016

Onconova Therapeutics, Inc.

By: /s/ Ramesh Kumar, Ph.D.
Name: Ramesh Kumar, Ph.D.
Title: Chief Executive Officer