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): **January 16, 2020**

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 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

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $.01 per share	ONTX	The Nasdaq Stock Market LLC
Warrants to purchase common stock	ONTXW	The Nasdaq Stock Market LLC

Item 1.02. Termination of a Material Definitive Agreement.

On May 10, 2019, Onconova Therapeutics, Inc. (the "Company") entered into a License and Collaboration Agreement (the "License Agreement") with HanX Biopharmaceuticals, Inc. ("HanX"). Under the terms of the License Agreement, the Company granted HanX an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Product") containing rigosertib in all uses of rigosertib or the Product in humans therapeutics uses (the "Field") in the People's Republic of China, Hong Kong, Macau and Taiwan (the "Territory"). In connection with the License Agreement, on May 10, 2019, the Company also entered into a Securities Purchase Agreement with each of HanX and Abundant New Investments Ltd. ("Abundant"), an affiliate of HanX (each, a "Securities Purchase Agreement" and together, the "Securities Purchase Agreements").

Section 8.1.2. of the License Agreement provides that in the event that the Company did not receive certain payments from HanX within 60 days of the License Agreement effective date, unless otherwise expressed waived in writing by the Company, the License Agreement and all rights and license granted to HanX under the License Agreement will be automatically deemed to be void *ab initio*. HanX did not make full payments required under Section 8.1.2, and the Company provided multiple waivers to provide HanX additional time to make payments. Effective January 16, 2020, the Company confirmed to HanX the Company's determination to no longer provide a waiver of HanX's failure to make full payments under Section 8.1.2. Accordingly, pursuant to Section 8.1.2 the agreement terminated. Upon this termination, the rights to Product in the Territory reverted to the Company in accordance with the terms of the License Agreement.

In addition, the Securities Purchase Agreements terminated automatically effective January 16, 2020 upon the termination of the License Agreement in accordance with Section 7.1(e) of the Securities Purchase Agreements.

The Company will not incur any termination penalties as a result of the termination of the License Agreement and the Securities Purchase Agreements.

A description of the terms and conditions of the License Agreement and the Securities Purchase Agreements is set forth in the Company's current report on Form 8-K filed with the SEC on May 16, 2019 and is incorporated herein by reference.

On January 23, 2020, the Company issued a press release announcing that the Company had regained the rights to rigosertib in Greater China, and that the License Agreement was terminated. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press Release dated January 23, 2020

EXHIBIT INDEX

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99.1	Press Release dated January 23, 2020

SIGNATURES

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: January 23, 2020

Onconova Therapeutics, Inc.

By: /s/ Mark Guerin
Name: Mark Guerin
Title: Chief Financial Officer

Exhibit 99.1

Onconova Therapeutics Regains Rigosertib Rights in Greater China

- Onconova has the rights to rigosertib, its lead Phase 3 drug candidate, in the key pharmaceutical markets of the United States, Europe, and Greater China

- The Company plans to partner certain available territories including Greater China in connection with the anticipated reporting of topline data from the registrational INSPIRE Trial in 1H 2020

- Rigosertib is partnered from agreements in 2019 with Knight Therapeutics for Canada, Specialised Therapeutics for Australia & New Zealand, and with Inceptua Medicines Access for a multi-country pre-approval access program. Onconova partnered rigosertib in 2018 with Pint Pharma for Latin America, and in 2011 with SymBio Pharmaceuticals for Japan & Korea

NEWTOWN, PA., January 23, 2020 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3-stage biopharmaceutical company discovering and developing novel products to treat cancer, with an initial focus on myelodysplastic syndromes (MDS), today announced that it has regained the rights to rigosertib in Greater China. Onconova regained the rights from HanX Biopharmaceuticals (HanX) as a result of the termination of the Onconova-HanX License Agreement pursuant to its terms due to HanX failing to make required payments under the agreement. In exchange for transition assistance and upon further regulatory, development and commercial progress in Greater China, HanX may be eligible to receive from Onconova incentive milestones and royalty payments. The Greater China territory, including mainland China, Hong Kong, Macau and Taiwan, represents one of the key world pharmaceutical markets.

“We are pleased to regain rigosertib rights for Greater China, and we are encouraged by the opportunity to partner rigosertib in select territories including Greater China as we approach the potential corporate catalyst of topline data for the registrational INSPIRE Trial in 1H 2020,” said Dr. Steven Fruchtman, President and Chief Executive Officer of Onconova. “We thank HanX for their collaborative efforts to advance rigosertib in this key market including the filing of the rigosertib IND in China.” Dr. Fruchtman continued, “In 2019, we added partners Knight Therapeutics for Canada, Specialised Therapeutics for Australia & New Zealand, and Inceptua Medicines Access in select countries for pre-approval access to our roster of global corporate partners, joining Pint Pharma for Latin America and SymBio Pharmaceuticals for Japan & Korea. The United States, Europe, and Greater China represent the major pharmaceutical markets Onconova directly controls heading into INSPIRE data read out.”

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer, with an initial focus on Myelodysplastic Syndromes (MDS). Using a proprietary chemistry platform, Onconova has created a pipeline of targeted agents designed to work against specific cellular pathways that are important in cancer cells. Advanced clinical trials with the Company’s lead compound, rigosertib, are aimed at what the Company believes are unmet medical needs of patients with MDS. Onconova has conducted trials with two other research compounds and has a pre-clinical program with a CDK4/6 and Ark5 inhibitor, ON 123300.

For more information, please visit http://www.onconova.com.

About Myelodysplastic Syndromes

Myelodysplastic syndromes (MDS) are conditions that can occur when the blood-forming cells in the bone marrow become dysfunctional and thus produce an inadequate number of circulating blood cells. It is frequently associated with the presence of blasts or leukemic cells in the marrow. This leads to low numbers of one or more types of circulating blood cells, and to the need for blood transfusions. In MDS, some of the cells in the bone marrow are abnormal (dysplastic) and may have genetic abnormalities associated with them. Different cell types can be affected, although the most common finding in MDS is a shortage of red blood cells (anemia). Patients with higher-risk MDS may progress to the development of acute leukemia.

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication in a preclinical model demonstrated rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinical development stage with oral and IV rigosertib, including clinical trials studying single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in first-line and refractory higher-risk MDS patients (Phase 2). Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

About the INSPIRE Phase 3 Clinical Trial

The clinical trial **IN**ternational **S**tudy of **P**hase 3 **I**V **R**igos**E**rtib, or **INSPIRE**, was finalized following guidance received from the U.S. Food and Drug Administration and European Medicines Agency. INSPIRE is a global, multi-center, randomized, controlled study to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who had progressed on, failed to respond to, or relapsed after previous treatment with a hypomethylating agent (HMA) within nine cycles over the course of one year after initiation of HMA treatment. This time frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. Patients are randomized at a 2:1 ratio into two study arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. The trial continued beyond the pre-specified interim analysis and is nearing its conclusion. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

About IV Rigosertib

The intravenous form of rigosertib has been studied in Phase 1, 2, and 3 clinical trials involving more than 1000 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with HR-MDS after failure of HMA therapy.

About Oral Rigosertib

The oral form of rigosertib was developed to provide a potentially more convenient dosage form for use where the duration of treatment may extend to multiple years. This dosage form may also support combination therapy modalities. To date, over 400 patients have been dosed with the oral formulation of rigosertib in clinical trials. Combination therapy of oral rigosertib with azacitidine, the standard of care in HR-MDS, has also been studied. Currently, oral rigosertib is being developed as a combination therapy together with azacitidine for patients with higher-risk MDS who require HMA therapy. A Phase 1/2 trial of the combination therapy has been fully enrolled, and the updated efficacy and safety data was presented at the ASH 2019 Annual Meeting in December 2019.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties. These statements relate to Onconova expectations regarding the INSPIRE Trial and Onconova's other development plans. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including Onconova's ability to continue as a going concern, maintain its Nasdaq listing, the need for additional financing, the success and timing of Onconova's clinical trials and regulatory approval of protocols, our collaborations including the effective termination of the HanX license and securities purchase agreements and plans for partnering certain territories, and those discussed under the heading "Risk Factors" in Onconova's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q. Any forward-looking statements contained in this release speak only as of its date. Onconova undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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