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 4, 2019**

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 3.01. Notice of Delisting or Failure to Satisfy a Continuing Listing Rule or Standard; Transfer of Listing.

On December 4, 2019, Onconova Therapeutics, Inc. (the "Company") received a letter from The Nasdaq Capital Market ("Nasdaq") indicating that the Company has failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a) (2) requires that companies listed on Nasdaq maintain a minimum closing bid price of at least $1.00 per share.

Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has a 180 calendar day grace period, or until June 1, 2020, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if the Company's common stock has a minimum closing bid price of at least $1.00 per share for a minimum of ten consecutive business days during the 180 calendar day grace period.

If the Company is not in compliance by June 1, 2020, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If the Company does not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. At that time, the Company may appeal the Nasdaq Staff's (the "Staff") determination to a Nasdaq Hearings Panel (the "Panel").

The Company intends to monitor the closing bid price of the Company's common stock and consider its available options to resolve the noncompliance with the minimum bid price requirement.

There can be no assurance that the Company will be able to regain compliance with the minimum stockholders' equity requirement, the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

On December 5, 2019, the Staff verbally advised the Company that it intends to issue a public reprimand letter to the Company in connection with the Company's public offering pursuant to a registration statement on Form S-1, as amended (Registration No. 333-234360) (the "Offering"), based on the Staff's belief that the offering did not meet the "public offering" criteria under the Staff's current interpretation of Rule 5635(d) of the Nasdaq Listing Rules.

As previously disclosed, as of September 30, 2019, the Company's total stockholders' equity was approximately $(6.0) million. As a result, the Company did not comply with the Nasdaq's $2.5 million minimum stockholders' equity requirement, nor the alternative compliance standards under Nasdaq Listing Rule 5550(b) for the continued listing of the Company's securities on Nasdaq. The Company requested a hearing which is scheduled for December 19, 2019 and submitted a plan of compliance to be reviewed with to the Panel. The Panel has the authority to grant the Company an additional extension of time of up to 180 calendar days from November 19, 2019 to regain compliance.

Item 8.01. Other Events

On December 5, 2019 (the "Effective Date"), the Company entered into a Pre-approval Access Program collaboration with Inceptua Medicines Access. On December 6, 2019 the Company issued a press release describing the collaboration which is attached hereto and incorporate herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press release issued by the Company dated December 6, 2019.

EXHIBIT INDEX

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99.1	Press release issued by the Company dated December 6, 2019.

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: December 6, 2019

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Inceptua Medicines Access and Onconova Therapeutics Announce
Pre-approval Access Collaboration for Rigosertib in Selected Countries Outside the US

NEWTOWN, PA., and LUXEMBOURG, Dec 6, 2019 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX) ("Onconova"), a Phase 3-stage biopharmaceutical company discovering and developing novel products to treat cancer, with an initial focus on myelodysplastic syndromes (MDS), and Inceptua Medicines Access (a business unit of the Inceptua Group), a global pharmaceutical company and service partner, today announced that they have entered into a collaboration to make available intravenous rigosertib via a Pre-approval Access Program in selected countries around the world.

Pre-approval Access Programs (also known as expanded access, early access, compassionate use, named patient supply) are regulatory-compliant processes permitting experimental agents in development to be made available upon the request of a physician or a patient for appropriate patients for whom no alternative treatment option exists in their country. Rigosertib is a small molecule that inhibits cellular signaling in cancer cells by acting as a RAS mimetic. Current clinical development of rigosertib is centered upon the therapeutic management of MDS, a heterogeneous group of bone marrow disorders characterized by ineffective hematopoiesis that often develop into acute myeloid leukemia (AML). Rigosertib, in its intravenous formulation, is currently in Phase 3 clinical development for the treatment of higher-risk MDS.

The rigosertib Pre-approval Access Program is expected to launch in first half of 2020 and will allow Inceptua to supply intravenous rigosertib within designated countries, primarily and initially concentrated in selected countries in Europe, in response to physician requests for patients with higher- risk MDS who have exhausted all available treatment options, and are not eligible for or have no access to the INSPIRE study. Under the terms of this agreement, Inceptua will support Onconova through the pre-approval provision of intravenous rigosertib initially into a number of countries including: Australia, Denmark, Finland, France, Ireland, Italy, the Netherlands, Portugal, South Africa, Spain, and the UK.

"Inceptua Medicines Access is delighted to be selected as Onconova's partner for the Pre-approval Access Program for rigosertib. Higher-risk MDS is a disease with significant unmet need, and we are pleased to be able to support healthcare professionals seeking access to rigosertib, ahead of its commercial launch," said Mark Corbett, EVP, Inceptua Medicines Access.

Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova, said, *"The rigosertib Pre-approval Access Program is a key strategic initiative for Onconova. We are pleased that intravenous rigosertib will be made compliantly available to suitable patients with higher-risk MDS through their physcians in designated countries. The program will run alongside our ongoing Phase 3 INSPIRE Trial, and is expected to continue until commercial launch in such countries. We are pleased to work with Inceptua, given their strong record of administering such programs successfully."*

Please note: Inceptua can only respond to unsolicited requests from bona fide healthcare professionals. Healthcare professionals can obtain information about the rigosertib Pre-approval Access Program by contacting Inceptua either by telephone +44 20 3910 7600 or by email: Access@inceptua.com.

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 preliminary efficacy and safety data was presented at The American Society of Hematology (ASH) Annual Meeting in December 2018. The data will be updated at the upcoming 2019 ASH Annual Meeting next week.

About Inceptua

Inceptua is a pharmaceutical company and service partner spanning throughout the product lifecycle – from comparator sourcing for clinical trials, through early access programs to licensing and commercialization for products.

We partner with life science companies of all sizes, drawing on over 20 years of industry experience. Our pharma and biotech offering includes registration and commercialization of products through in-licensing and flexible partnerships. We have leading expertise in strategy and operational implementation of pre-approval access programs making pharmaceutical products under clinical development available for patients and Inceptua's clinical trial services business offers high quality clinical comparator sourcing and manufacturing services with an agile global supply chain to ensure that products are delivered exactly when needed.

Inceptua Medicines Access is a business unit of the Inceptua Group. It offers full access solutions for the design, implementation and delivery of Pre-approval and Medicines Access Programs on behalf of biopharmaceutical companies.

Inceptua has global operations with local offices across Europe, USA, and Asia.

www.inceptua.com

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, 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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