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 9, 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 7.01 Regulation FD Disclosure.

On December 9, 2019, Onconova Therapeutics, Inc. ("Onconova" or the "Company") issued a press release announcing data presented from INSPIRE related abstracts at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, FL. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference. The presentation materials will be available on the Company's website.

The information disclosed under this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Forward Looking Statements

Some of the statements in this report 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 the Company's expectations regarding the INSPIRE Trial and Onconova's other development plans. The Company 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 the Company 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 the Company's ability to continue as a going concern, the need for additional financing, the success and timing of the Company's clinical trials and regulatory approval of protocols, our collaborations and those discussed under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q.

Any forward-looking statements contained in this report speak only as of its date. The Company undertakes no obligation to update any forward-looking statements contained in this report to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release of Onconova Therapeutics, Inc. issued on December 9, 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 9, 2019

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Announces Data on Genomic Profiles of Higher Risk Myelodysplastic Syndromes Patients Refractory to Azacitidine Therapy Enrolled into the Pivotal INSPIRE Trial and Updated Oral Rigosertib Data Informing a Potential Adaptive Clinical Trial Design at the American Society of Hematology 2019 Annual Meeting

- Genomic Profiling at Study Entry in Patients with Higher Risk Myelodysplastic Syndrome (HR-MDS) Following Hypomethylating (HMA) Failure: Results From the INSPIRE Trial, including RAS and other Mutations
- New Data Presented at the ASH 2019 Annual Meeting Provides Insights for Potential Future Development Plans for Oral Rigosertib
- Oral Presentation of Updated Data on the Novel Combination of Oral Rigosertib + Azacitidine (AZA) Versus Single Agent AZA in Treatment-Naive Patients with HR-MDS
- 3 Additional Abstract Presentations at ASH 2019 Annual Meeting

NEWTOWN, PA., Dec 9, 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), today announced data presented from INSPIRE related abstracts at the American Society of Hematology (ASH) 2019 Annual Meeting. Preliminary genomics data from the INSPIRE Trial was presented. In addition, updated data from the Phase 2 Trial of Oral Rigosertib + Azacitidine (AZA) Versus Single Agent AZA in Treatment-Naive Patients with HR-MDS was presented in an oral presentation. The Company believes these abstracts represent important progress for the development programs of intravenous (IV) and oral rigosertib.

Abstract # 3015. "Genomic Profiling in Patients with Higher Risk Myelodysplastic Syndrome Following HMA Failure: Baseline Results From the INSPIRE Trial." At study entry, 50 different mutations were identified at baseline prior to patients receiving study treatment with either IV rigosertib or physician's choice (PC). The average number of mutations per patient was 3. The most common mutations identified in patients were ASXL1 39%, TP53 27%, RUNX1 25%, STAG2 21%, SRSF2 19%, TET2 19%, DNM3A 15%, IDH2 13% and U2AF1 12%. In total 31 patients (19%) had mutations that are part of RAS pathway (NRAS, 4 pts; KRAS, 5 pts; CBL, 7 pts; PTPN11, 7 pts; NF1, 8 pts).

"Genomic abnormalities have revolutionized our understanding of the biology and prognosis of patients with MDS. Abnormalities involving the RAS pathway are seen in patients with MDS who have a very poor prognosis. The INSPIRE Trial has catalogued the abnormalities seen in patients with MDS who have failed the standard of care AZA. On-going studies will determine if the research drug rigosertib can target these abnormalities and prolong the lives of patients who have the spectrum of abnormalities that have been identified." said Guillermo Garcia-Manero, M.D., Department of Leukemia, The University of Texas MD Anderson Cancer Center.

Abstract #4249. "Phase II Study of Oral Rigosertib Combined with Azacitidine As First Line Therapy in Patients with HR-MDS." In HMA naïve higher risk MDS patients who require the standard of care with AZA, the combination of oral rigosertib $\geq$ 840 mg and AZA produced an overall response rate of 90% and a complete response (CR) rate of 34%. CR by definition signifies the patient has a normal appearing bone marrow and the marrow produces a normal peripheral blood count. The median duration of response is 12.2 months. The Company believes these data support the design of a planned Phase 2/3 adaptive trial in HR-MDS.

“Efforts to improve the response rate with single agent AZA is an area of active research. The efficacy and safety data of the doublet of oral rigosertib and AZA warrants further investigation in a pivotal trial of this novel combination compared to AZA alone. If the preliminary efficacy of the doublet is confirmed in a pivotal controlled study and has an acceptable safety profile, patients with HMA naïve higher risk MDS may have an important new treatment option.” said Lewis Silverman, M.D. Director of Translational Research Center for MDS, Division of Hematology/Oncology, at the Icahn School of Medicine at Mount. Sinai.

Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova, said, “ASH 2019 was a key milestone for Onconova. The five presentations at ASH showcase the value of our development programs for intravenous and oral rigosertib. The genomic data from the INSPIRE Trial identifies the most common mutations in HR-MDS following AZA failure, including those of the RAS pathway that are targeted by rigosertib. We believe the oral rigosertib in combination with AZA Phase 2 data forms the foundation of a future adaptive trial in HMA naïve HR-MDS patients. We appreciate the recognition by ASH reviewers of the value of our studies in this field.”

Three additional abstracts being presented at the ASH 2019 Annual Meeting include:

Abstract #4249. “The Inspire Study in HR MDS: A Novel Phase 3 Study Adaptive Design for Hematological Malignancies in Adults.”

Abstract #4268. “Phase 3, Multi-Center, International, Randomized, Double-Blind, Placebo Controlled Study of Oral Rigosertib + Injectable Azacitidine (AZA) Versus Injectable Azacitidine in Treatment-Naïve Patients with Higher-Risk Myelodysplastic Syndrome (HR-MDS).”

Abstract #4231. “The Sequenced Combination of Rigosertib and Azacitidine Has Modulatory Effects on CXCL8, RIG-I like Receptor (RLR) and Wnt/β-Catenin Signaling and Downstream Hematopoiesis Pathways in an in Vitro Model of the Myelodysplastic Syndrome.”

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 described 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

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