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 17, 2018**

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. ☐

Item 8.01. Other Events.

On January 17, 2018, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing that it is moving forward with its Phase 3 INSPIRE pivotal trial following the interim analysis, consistent with the recommendation of the Independent Data Monitoring Committee ("DMC"). The DMC recommended continuation of the trial with a one-time expansion in enrollment, using a pre-planned sample size re-estimation, consistent with the Statistical Analysis Plan ("SAP"). The INSPIRE pivotal trial is studying intravenously-administered (IV) rigosertib in patients with higher-risk myelodysplastic syndromes ("MDS") who have progressed on, failed to respond to, or relapsed after prior hypomethylating agent ("HMA") therapy. The Company remains blinded to the interim analysis results.

The SAP for the INSPIRE trial featured an adaptive trial design, permitting several options following the interim analysis, which included continuation of the trial as planned, discontinuation of the trial for futility, trial expansion using pre-planned sample size re-estimation, and trial continuation for only the pre-defined treatment subgroup of patients classified as Very High Risk ("VHR") based on the Revised International Prognostic Scoring System (IPSS-R).

The expanded INSPIRE study will continue to enroll eligible patients based on the current trial design of the overall Intent To Treat ("ITT") population and will increase enrollment by adding 135 patients to the original target to reach a total enrollment of 360 patients, with the aim of increasing the power of the trial. Due to the adaptive trial design and the DMC's assessment, the INSPIRE trial will continue to analyze both the ITT and the VHR population for the primary endpoint of overall survival. The design of the trial with the expanded study enrollment will be identical to the current study design and will include the analysis of the overall survival endpoint in the ITT and the pre-specified VHR subgroup.

Currently, the INSPIRE study is active at approximately 175 trial sites in 22 countries across four continents, and has enrolled more than 170 patients. In Japan, patients have been enrolled to this study by SymBio Pharmaceuticals, the Company's collaboration partner for Japan and Korea. The Company believes that this trial is the most advanced study for a new therapeutic agent in this indication, and there are no FDA approved therapies specifically for MDS patients after failure of front-line HMAs.

A copy of the press release is attached as Exhibit 99.1 hereto.

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. 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. 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. 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 and current plans and future needs to scale back operations if adequate financing is not obtained, the success and timing of the Company's clinical trials and regulatory approval of protocols, 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

Exhibit No.	Exhibit
99.1	Press release dated January 17, 2018

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated January 17, 2018

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 17, 2018

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Moving Forward with Phase 3 INSPIRE Pivotal Trial with Increased Sample Size Following Promising Interim Analysis

January 17, 2018

- *Independent Data Monitoring Committee (DMC) recommends continuation of INSPIRE trial with trial expansion per adaptive design based on interim analysis results for overall survival*
- *Trial Executive Committee unanimously agreed to continue the Intent To Treat (ITT) study population and increase clinical trial enrollment by adding 135 patients to the original target of 225 patients, based upon the DMC's recommendations*
- *In the INSPIRE trial enrollment so far, the predefined subgroup of Very High Risk (VHR) patients constitutes greater than 70% of patients enrolled to date*
- *Onconova to host conference call discussing interim results today at 8.30am ET*

NEWTOWN, Pa., Jan. 17, 2018 (GLOBE NEWSWIRE) — Onconova Therapeutics, Inc. (Nasdaq:ONTX), a Phase 3-stage biopharmaceutical company focused on discovering and developing small molecule drug candidates to treat cancer, today announced that it is moving forward with its Phase 3 INSPIRE pivotal trial following the interim analysis, consistent with the DMC's recommendation. The DMC recommended continuation of the trial with a one-time expansion in enrollment, using a pre-planned sample size re-estimation, consistent with the Statistical Analysis Plan (SAP). The INSPIRE pivotal trial is studying intravenously- administered (IV) rigosertib in patients with higher-risk myelodysplastic syndromes (MDS) who have progressed on, failed to respond to, or relapsed after prior hypomethylating agent (HMA) therapy. The Company remains blinded to the interim analysis results.

Guillermo Garcia-Manero, M.D, Professor and Chief of the MDS Section at the MD Anderson Cancer Center, a lead investigator on the INSPIRE study, commented, "Choices are very limited for higher risk MDS patients after failure of HMA therapy and no second-line therapy has ever been approved by the Health Authorities for these patients. These patients have a very short life-span and there is a tremendous unmet medical need. We remain highly supportive of Onconova's efforts. After the interim analysis, continuation of the INSPIRE study is encouraging for patients."

The SAP for the INSPIRE trial featured an adaptive trial design, permitting several options following the interim analysis, which included continuation of the trial as planned, discontinuation of the trial for futility, trial expansion using pre-planned sample size re-estimation, and trial continuation for only the pre-defined treatment subgroup of patients classified as VHR based on the Revised International Prognostic Scoring System (IPSS-R).

The expanded INSPIRE study will continue to enroll eligible patients based on the current trial design of the overall ITT population and will increase enrollment by adding 135 patients to the original target to reach a total enrollment of 360 patients, with the aim of increasing the power of the trial. Due to the adaptive trial design and the DMC's assessment, the INSPIRE trial will continue to analyze both the ITT and the VHR population for the primary endpoint of overall survival. The design of the trial with the expanded study enrollment will be identical to the current study design and will include the analysis of the overall survival endpoint in the ITT and the pre-specified VHR subgroup.

Steve Fruchtman, M.D., Chief Medical Officer of Onconova, added, "With no FDA approved therapies for many patients with higher-risk MDS who are refractory to HMAs, we are encouraged by these results and pleased to be at the forefront of advances in this treatment landscape. The DMC's recommendation based on the pre-planned interim analysis includes the expansion of the INSPIRE trial and retains the analysis of survival in both the ITT and the VHR pre-defined subgroups. Patients with MDS who are refractory to HMAs have the highest unmet medical need due to an extremely poor prognosis following failure of HMA therapy. We look forward to completing enrollment and for the opportunity to analyze overall survival in the higher-risk MDS patients who have failed prior HMA therapy."

Currently, the INSPIRE study is active at approximately 175 trial sites in 22 countries across four continents, and has enrolled more than 170 patients. In Japan, patients have been enrolled to this study by SymBio Pharmaceuticals, our collaboration partner for Japan and Korea. Onconova believes that this trial is the most advanced study for a new therapeutic agent in this indication, and there are no FDA approved therapies specifically for MDS patients after failure of front-line HMAs.

The Company will host a conference call today, January 17th at 8:30 a.m. Eastern Time to discuss the interim results and answer any questions. Interested parties may access the call by dialing toll-free (855) 428-5741 from the US, or (210) 229-8823 internationally and using conference ID: 8899928.

The call will also be webcast live. Please click here to access the webcast.

A replay will be available at this link until April 30, 2018.

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 a primary focus on Myelodysplastic Syndromes (MDS). Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule agent, which we believe blocks cellular signaling by targeting RAS effector pathways. 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. Onconova has three product candidates in the clinical stage and several pre-clinical programs. 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. For more information, please visiht ttp://www.onconova.com.

About IV Rigosertib

The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trials involving more than 800 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **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 and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first 9 months or 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. Following interim analysis in early 2018, the independent Data Monitoring Committee recommended that the trial continue with an expansion in enrollment to 360 patients based on a pre-planned sample size re-estimation. Patients are randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. 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 Oral Rigosertib

The oral form of rigosertib was developed to provide more convenient dosing for use where the duration of treatment may extend to multiple years. This dosage form may also support many combination therapy modalities. To date, 368 patients have been treated with the oral formulation of rigosertib. Initial studies with single-agent oral rigosertib were conducted in hematological malignancies, lower-risk MDS, and solid tumors. Combination therapy of oral rigosertib with azacitidine and chemoradiotherapy has also been explored. 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 results were presented in 2016. This novel combination is the subject of an issued US patent with earliest expiration in 2028.

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 Therapeutics, Inc.'s expectations regarding the INSPIRE Trial. 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. 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. 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, the need for additional financing and current plans and future needs to scale back operations if adequate financing is not obtained, the success and timing of Onconova's clinical trials and regulatory approval of protocols, 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.

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Source: Onconova Therapeutics, Inc.