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): **August 24, 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 filing 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 (17 CFR 230.425)

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

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

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

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
Common Stock Warrants	ONTXW	The Nasdaq Stock Market LLC

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 ☐

Item 7.01. Regulation FD Disclosure.

On August 24, 2020, Onconova Therapeutics, Inc. (“Onconova” or the “Company”) issued a press release announcing topline results from the Company’s pivotal Phase 3 INSPIRE trial. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

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.

Item 8.01. Other Events.

On August 24, 2020, Onconova announced topline results from its pivotal Phase 3 INSPIRE trial, which assessed the efficacy and safety of IV rigosertib in higher-risk MDS (“HR-MDS”) patients. The trial did not meet its primary endpoint of improved survival.

The primary endpoint of the trial was overall survival, comparing IV rigosertib plus best supportive care to physician's choice (“PC”) plus best supportive care in 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. A pre-specified analysis in the very high risk (“VHR-MDS”) patient subgroup was also conducted.

Results of INSPIRE demonstrated that in the intent-to-treat analysis patients randomized to IV rigosertib resulted in overall survival of 6.4 months, versus 6.3 months for PC (p=0.33) in the overall HR-MDS population. Overall survival in the pre-specified VHR-MDS subgroup of patients was also not significantly different between the two study arms. There was an increase in overall survival in the PC arm post-interim analysis that was unexpected. The Company is conducting additional analyses.

Safety analysis indicates that IV rigosertib was generally well tolerated, with reported adverse events similar to those observed in previous clinical studies with IV rigosertib in MDS. Serious adverse events (“SAEs”) were uncommon, with a similar profile of SAEs in both study arms.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	**Description**
99.1	Press release of Onconova Therapeutics, Inc. issued on August 24, 2020

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: August 24, 2020

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Announces Topline Results from the Pivotal Phase 3 INSPIRE Trial

IV rigosertib did not meet primary endpoint of significantly improved survival versus best supportive care in higher-risk myelodysplastic syndromes (HR-MDS)

Onconova will focus on promising pipeline opportunities including with its CDK4/6 + ARK5 inhibitor ON 123300

Onconova to host conference call today at 8:30 a.m. ET

NEWTOWN, Pa., August 24, 2020 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX) a biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced that INSPIRE, the company's pivotal Phase 3 study assessing the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients, did not meet its primary endpoint of improved survival.

"Onconova would like to thank the MDS community for its participation in the INSPIRE trial. We report these results with great disappointment, and we remain deeply indebted to every patient, physician, and family member involved in the study," said Steven M. Fruchtman, M.D., President and Chief Executive Officer. "Onconova is fortunate to have built a product pipeline that includes multiple promising agents, including oral rigosertib and ON 123300. Both compounds target meaningful cancer pathways, and we look forward to further efforts with these programs. The Company will review pipeline and in-licensing opportunities both internally and with external advisors."

The primary endpoint of the trial was overall survival, comparing IV rigosertib plus best supportive care to physician's choice (PC) plus best supportive care in 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. A pre-specified analysis in the very high risk (VHR-MDS) patient subgroup was also conducted.

Results of INSPIRE demonstrated that in the intent-to-treat analysis patients randomized to IV rigosertib achieved overall survival of 6.4 months, versus 6.3 months for PC ($p=0.33$) in the overall HR-MDS population. Overall survival in the pre-specified VHR-MDS subgroup of patients was also not significantly different between the two study arms. There was an increase in overall survival in the PC arm post-interim analysis that was unexpected. The Company is conducting additional analyses.

Safety analysis indicates that IV rigosertib was generally well tolerated, with reported adverse events similar to those observed in previous clinical studies with IV rigosertib in MDS. Serious adverse events (SAEs) were uncommon, with a similar profile of SAEs in both study arms.

"While the INSPIRE data readout in HR-MDS is a disappointment, as a RAS pathway inhibitor oral rigosertib could address a number of oncology settings outside of hematology," said Richard C. Woodman, M.D., Chief Medical Officer of Onconova. "We plan to take learnings from genomic analyses of the INSPIRE trial to inform the future development of rigosertib. We also look forward to the continued expansion of the investigator-initiated study program with oral rigosertib beyond the ongoing Phase 1/2a study in KRAS+ lung adenocarcinoma into additional solid tumors. Our novel CDK4/6 + ARK5 inhibitor, ON 123300, could also represent a meaningful advance over existing products."

The Company will host a conference call today, August 24, 2020, at 8:30 a.m. Eastern Time. Interested parties who wish to participate in the conference call may do so by dialing (855) 428-5741 for domestic callers and (210) 229-8823 for international callers, and using conference ID 8087044.

To facilitate an on-time conference call start, Onconova recommends that participants dial in 15 minutes before the 8:30 a.m. ET start time.

Those interested in listening to the conference call via the internet may do so by visiting the investors and media page on the company's website at www.onconova.com and clicking on the webcast link. In addition to the live webcast, a replay will be available on the Onconova website for 90 days following the call.

About Onconova Therapeutics, Inc.
Onconova Therapeutics is a biopharmaceutical company focused on discovering and developing novel drugs to treat cancer. Onconova has a pipeline of proprietary targeted agents designed to work against specific cellular pathways that are important in cancer cells. Clinical trials with the Company's compound rigosertib are aimed at what the Company believes are unmet medical needs of patients with cancer. 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 https://www.onconova.com.

About Rigosertib
Rigosertib, Onconova's lead candidate, is a proprietary small molecule. A key publication in a preclinical model reported 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). Preclinical work with rigosertib is underway in COVID-19. Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

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. In addition, an investigator-initiated Phase 1/2a study in KRAS+ lung adenocarcinoma is ongoing.

About INSPIRE
The clinical trial **IN**ternational **S**tudy of **P**hase 3 IV **R**igos**E**rtib, or INSPIRE, was finalized following guidance received from the U.S. Food and Drug Administration and European Medicines Agency. INSPIRE was 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 for the opportunity to respond to treatment with an HMA prior to declaring treatment failure is per the NCCN Guidelines. Patients were 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 was 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).

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 its clinical development plans and patents. 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 the success and timing of Onconova's clinical trials and regulatory approval of protocols, Onconova's ability to continue as a going concern, the need for additional financing, 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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