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): **May 14, 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

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

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 2.02 Results of Operations and Financial Condition.

On May 14, 2020, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2020, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference. The information contained in this Form 8-K (including the exhibit hereto) 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit
99.1	Press release issued by the Company dated May 14, 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: May 14, 2020

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Provides Corporate Update and Reports First Quarter 2020 Financial Results

Conference Call and Webcast Scheduled Today, May 14 at 4:30 p.m. ET

NEWTOWN, Pa., May 14, 2020 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3 stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with an initial focus on myelodysplastic syndromes (MDS), today reported financial results for the quarter ended March 31, 2020, and provided a business update.

“With enrollment completed in March, Onconova’s pivotal Phase 3 INSPIRE trial is advancing to the next catalyst. We are fortunate to have achieved full enrollment of INSPIRE prior to the pandemic-driven disruptions to research studies at hospitals and cancer centers across the globe,” said Steven M. Fruchtman, M.D., President and Chief Executive Officer. “Based on survival trends in the INSPIRE trial, we continue to anticipate reporting topline survival data in the second half of 2020. We expect to present the results of this trial at a major medical meeting later this year.”

Dr. Fruchtman continued, “Beyond INSPIRE, we are primed for additional progress, including the to be initiated Phase 1/2a study of rigosertib plus nivolumab in Stage IV KRAS mutated lung adenocarcinoma, following the renewal of clinical cancer research programs post their COVID-mandated stoppage, as well as additional planned studies of rigosertib and our pipeline programs. We are preparing for and look forward to multiple corporate milestones in the second half of 2020.”

First Quarter 2020 Developments and Recent Highlights

- Completed enrollment of the pivotal Phase 3 INSPIRE trial
- Opened investigator-initiated study of rigosertib plus nivolumab in Stage IV KRAS mutated lung adenocarcinoma
- Re-acquired rights to rigosertib in Greater China
- Next generation CDK 4/6 + ARK5 inhibitor, ON123300, IND approved in China
- Nominated life sciences industry veteran Terri Shoemaker to the Company’s Board of Directors

Additional Upcoming Company Milestones Expected

- Pivotal survival data from the INSPIRE trial expected in 2H 2020
- European Hematology Association Virtual Congress presentation in June 2020:
    - Mutations in RAS Pathway Genes Correlates with Type of Failure to Azacitidine: Genomic Analysis at Randomization onto the Inspire Trial (EHA-4044)
- Type C meeting to be requested in 2Q 2020 for a randomized Phase 2/3 study of the combination of oral rigosertib plus azacitidine
- Expansion of the rigosertib investigator-initiated program to include KRAS mutated non-small cell lung cancer, melanoma and other RAS mutated-driven cancers
- Next generation CDK 4/6 + ARK5 inhibitor, ON123300, US IND submission planned for 4Q 2020, and Phase 1 study commencement in China planned for 2H 2020
- Anticipated launch of Early Access Program with Inceptua Medicines Group in 2H 2020

First Quarter 2020 Financial Results

Cash and cash equivalents as of March 31, 2020, totaled $31.0 million, compared to $22.7 million as of December 31, 2019. Common stock warrant exercises since our financing transaction in November 2019 have added $10.6 million to our balance sheet. Of the almost 29 million common stock warrants outstanding as of March 31, 2020, over 80% of them were in-the-money as of May 13th. Based on current projections, the Company continues to expect that its cash and cash equivalents as of March 31, 2020 will be sufficient to fund ongoing trials and operations into the third quarter of 2021.

Net loss was $5.1 million for the quarter ended March 31, 2020, compared to $7.6 million for the quarter ended March 31, 2019. Research and development expenses were $3.4 million for the quarter ended March 31, 2020 and $4.1 million for the comparable period in 2019. General and administrative expenses were $1.8 million for the quarter ended March 31, 2020 and $3.2 million for the comparable period in 2019.

Conference Call and Webcast Information

The Company will host a conference call today, May 14, 2020, at 4:30 p.m. Eastern Time, to provide a corporate update and discuss first quarter 2020 financial results. Interested parties may access the call by dialing toll-free (855) 428-5741 from the U.S., or internationally (210) 229-8823 and using conference ID 3488818. The call will also be webcast live. Please click here to access the webcast. A replay will be available following the live webcast.

To facilitate an on-time conference call start, Onconova recommends that participants dial in 15 minutes before the 4:30 p.m. ET start time.

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel drugs to treat cancer, with an initial focus on myelodysplastic syndromes (MDS). Onconova has a pipeline of proprietary 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 https://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 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). 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 HMA-naïve 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 (**INSPIRE**) was finalized following guidance received from the U.S. Food and Drug Administration and the 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 1,200 patients, and is currently being evaluated in a randomized Phase 3 international trial (INSPIRE) 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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TABLES FOLLOW

ONCONOVA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 31,036	$ 22,726
Receivables	45	98
Prepaid expenses and other current assets	795	650
Total current assets	31,876	23,474
Property and equipment, net	47	50
Other non-current assets	150	150
Total assets	$ 32,073	$ 23,674
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,183	$ 4,271
Accrued expenses and other current liabilities	2,501	3,795
Deferred revenue	226	226
Total current liabilities	6,910	8,292
Warrant liability	176	113
Deferred revenue, non-current	3,639	3,695
Total liabilities	10,725	12,100
Stockholders' equity:		
Preferred stock	-	-
Common stock	1,674	1,112
Additional paid in capital	428,189	413,879
Accumulated other comprehensive loss	(24)	(18)
Accumulated deficit	(408,491)	(403,399)
Total stockholders' equity	21,348	11,574
Total liabilities and stockholders' equity	$ 32,073	$ 23,674

ONCONOVA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations *(unaudited)*
(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2020	**2019**
Revenue	$ 52	$ 68
Operating expenses:		
General and administrative	1,807	3,234
Research and development	3,370	4,075
Total operating expenses	5,177	7,309
Loss from operations	(5,125)	(7,241)
Change in fair value of warrant liability	(63)	(427)
Interest income	96	68
Net loss	(5,092)	(7,600)
Net loss per share of common stock, basic and diluted	$ (0.03)	$ (1.29)
Basic and diluted weighted average shares outstanding	160,346,087	5,890,098