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): **March 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 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 March 24, 2020, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2019, 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 March 24, 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: March 24, 2020

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Announces Completion of Enrollment of Phase 3 INSPIRE Trial, Provides a Corporate Update, and Reports 2019 Financial Results

NEWTOWN, Pa., March 24, 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 year ended December 31, 2019 and provided a corporate update.

“Following significant progress throughout 2019, our team’s immediate focus remains to advance our pivotal Phase 3 INSPIRE trial to the next milestone” said Steven M. Fruchtman, M.D., President and Chief Executive Officer. “We are excited to announce the completion of the planned enrollment of 360 patients in the INSPIRE trial in higher-risk (HR) MDS patients. INSPIRE represents one of the largest studies ever conducted in this patient population. Based on survival trends on the INSPIRE trial to date, we anticipate reporting topline survival data in the second half of 2020 and presenting the results at a medical meeting later this year. We continue to analyze deep genomic sequencing, including mutations of the Ras pathway, on these patients. Important genomic results were presented at ASH 2019 and additional data is expected to be presented at future medical meetings.”

Dr. Selina Luger, M.D., Professor of Medicine at the Hospital of the University of Pennsylvania Division of Hematology Oncology, commented, “in second line HR MDS, following progression or failure of patients to respond to hypomethylating agents, there is no standard of care and currently no health authority approved agent in the world. There is a tremendous unmet medical need for these patients. The INSPIRE trial, which has now reached full accrual, is studying the experimental agent rigosertib to determine if it can significantly prolong the survival of these patients when compared to physician’s choice of therapy. We eagerly look forward to the results of this pivotal trial.”

Dr. Fruchtman continued, “We are also pleased about the progress of our plans for additional investigator-initiated studies – including the Phase 1/2a study of rigosertib plus nivolumab for the treatment of Stage IV KRAS mutated lung adenocarcinoma. We anticipate the first patient to be entered onto the trial once the COVID-19 environment improves sufficiently.”

Fourth Quarter 2019 and Additional Achievements

- Knight Therapeutics License for Rigosertib in Canada
- Specialised Therapeutics License for Rigosertib in Australia and New Zealand
- Inceptua Medicines Pre-approval Access Collaboration for Rigosertib in Selected Countries Outside the US
- Re-acquired Rigosertib Rights in Greater China
- Next generation CDK 4/6 + ARK5 inhibitor, ON123300, IND approved in China

Additional Milestones for Rigosertib and Pipeline Products

- Clinical trial protocol progressing for a randomized Phase 2/3 study of the combination of oral rigosertib plus azacitidine
- Expansion of the rigosertib investigator-initiated studies 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 in 4Q 2020
- Pivotal survival data from the INSPIRE trial expected in 2H 2020

Full Year 2019 Financial Results

Cash and cash equivalents as of December 31, 2019, totaled $22.7 million, compared to $17.0 million as of December 31, 2018. Besides the $9 million of net proceeds from the financing closed in early 2020, common stock warrant exercises since 12/31/19 have added $5.7 million to the Company's cash balance resulting in a cash balance at February 29, 2020 of $32.6 million. Based on current projections, the Company expects that cash and cash equivalents will be sufficient to fund ongoing trials and operations into the third quarter of 2021.

Net loss was $21.5 million for the year ended December 31, 2019, compared to $20.4 million for the year ended December 31, 2018. Research and development expenses were $15.5 million for the year ended December 31, 2019 and $16.9 million for the comparable period in 2018. General and administrative expenses were $8.3 million for the year ended December 31, 2019 and $7.6 million for the comparable period in 2018.

Conference Call and Webcast Information

The Company will host a conference call today, March 24, 2020, at 4:30 p.m. Eastern Time, to provide a corporate update and discuss year-end 2019 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 3267259. The call will also be webcast live. Please click here to access the webcast. A replay will be available following the live webcast.

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 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 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 naive 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

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.

Press release contact information

Company Contact:
Avi Oler
Onconova Therapeutics, Inc.
267-759-3680
ir@onconova.us
https://www.onconova.com/contact/

Media
David Schull, Russo Partners LLC: (212) 845-4271
Nic Johnson, Russo Partners LLC: (212) 845-4242

Investors
Jan Medina, CFA, Russo Partners LLC: (646) 942-5632

TABLES FOLLOW

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	December 31, 2019	December 31, 2018
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 22,726	$ 16,970
Receivables	98	35
Prepaid expenses and other current assets	650	760
Total current assets	23,474	17,765
Property and equipment, net	50	9
Other non-current assets	150	149
Total assets	$ 23,674	$ 17,923
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,271	$ 4,039
Accrued expenses and other current liabilities	3,795	4,173
Deferred revenue	226	226
Total current liabilities	8,292	8,438
Warrant liability	113	176
Deferred revenue, non-current	3,695	3,922
Total liabilities	12,100	12,536
Stockholders' equity:		
Preferred stock	-	-
Common stock	1,112	57
Additional paid in capital	413,879	387,238
Accumulated other comprehensive income	(18)	(12)
Accumulated deficit	(403,399)	(381,896)
Total Onconova Therapeutics Inc. stockholders' equity	11,574	5,387
Non-controlling interest	-	-
Total stockholders' equity	11,574	5,387
Total liabilities and stockholders' equity	$ 23,674	$ 17,923

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations *(unaudited)*

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	**2018**
	(unaudited)	
Revenue	$ 2,183	$ 1,228
Operating expenses:		
General and administrative	8,345	7,586
Research and development	15,537	16,924
Total operating expenses	23,882	24,510
Loss from operations	(21,699)	(23,282)
Change in fair value of warrant liability	63	1,597
Other income, net	143	1,151
Net loss before income taxes	(21,493)	(20,534)
Income tax (benefit) expense	10	(124)
Net loss	(21,503)	(20,410)
Net gain attributable to non-controlling interest	-	(163)
Net loss attributable to Onconova Therapeutics, Inc.	$ (21,503)	$ (20,573)
Net loss per share of common stock, basic and diluted	$ (1.49)	$ (4.99)
Basic and diluted weighted average shares outstanding	14,384,476	4,124,073