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 14, 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 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 ☐

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 August 14, 2019, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and six months ended June 30, 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.

99.1 Press release issued by the Company dated August 14, 2019.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by the Company dated August 14, 2019.

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 14, 2019

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics, Inc. Reports Business Highlights and Second Quarter 2019 Financial Results

NEWTOWN, Pa., August 14, 2019 — Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3 stage biopharmaceutical company discovering and developing novel products to treat cancer, with a focus on Myelodysplastic Syndromes (MDS), today provided a corporate update and reported financial results for the second quarter ended June 30, 2019.

Steven M. Fruchtman, M.D., President and Chief Executive Officer, stated, "Enrollment in our global Phase 3 INSPIRE Trial with IV rigosertib in second-line, higher-risk MDS patients is progressing. Our goal is to complete enrollment by the end of 2019 and we anticipate reporting top-line data in the first half of 2020 following full enrollment and 288 death events. If the INSPIRE Trial is successful, we believe rigosertib could be the first new treatment for higher-risk MDS in more than 15 years, and based on its unique mechanism of action, has the potential to provide clinical benefit in other Ras mutated cancers."

Dr. Fruchtman continued, "In addition to advancing the INSPIRE Trial, our Special Protocol Assessment (SPA) request to the FDA for a Phase 3 combination trial of oral rigosertib plus azacitidine in first-line higher-risk MDS patients is being pursued. We also have plans to target cancers driven by mutated Ras genes. Ras-mutated cancers represent about a third of all human cancers, and a Phase 1 study of rigosertib in combination with a PD-1 inhibitor for patients with progressive K-Ras mutated non-small cell lung cancer is expected to commence in 2019 as an investigator-initiated study. We are also working toward filing an IND for a Phase 1 trial of ON 123300, our investigational, first-in-class, dual inhibitor of CDK4/6 + ARK5, which we believe has the potential to treat various cancers including refractory metastatic breast cancer."

Second Quarter 2019 and Recent Highlights

- On March 25, the Company announced that it had passed the 75 percent enrollment mark in the Phase 3 INSPIRE Trial. Onconova remains focused on our primary goal of completing enrollment by the end of 2019 and expects to report top-line survival data following full enrollment and 288 death events.

    - More than 140 trial sites in 24 countries across four continents are open, including 21 sites in Japan. The Company opened new clinical trial sites in already participating countries. Additional geographies, including Brazil, are being opened during the coming months to add approximately 25 more sites. This strategy is designed to support the goal of achieving full accrual to the INSPIRE Trial in 2019. The Company anticipates reporting top-line data in the first half of 2020 following full enrollment and 288 death events.

- The Company entered into a license agreement with HanX Biopharmaceuticals (HanX) for the development and commercialization of rigosertib in Greater China. The agreement provides for

$4 million of upfront payments to Onconova, including a $2 million cash upfront fee and an investment totaling $2 million in shares purchased at a premium to market. In addition, HanX agreed to place $2 million in escrow in local currency for rigosertib clinical development expenses in Greater China. HanX will make additional regulatory, developmental, and sales-based milestone payments to Onconova of up to $45.5 million and will pay Onconova tiered royalties up to double digits on net sales in Greater China. If approval is received, Onconova will supply rigosertib to HanX for development and commercialization. HanX also will support Onconova's other clinical trial initiatives in Greater China.

- Onconova and Mission Bio have entered into a collaboration to utilize the Mission Bio Tapestri® Platform for targeted single-cell DNA analysis to study rigosertib as part of planned clinical trials. Single-cell genomics may identify mutations with far better resolution than that of traditional sequencing methods, allowing a view into each patient's disease at a level never before achieved. Tapestri will be utilized to identify mutations, including those of the Ras pathway, to monitor a patient's response in clinical trials, supporting the advancement of rigosertib. By adding the Tapestri Platform to its research and development program, Onconova is including the opportunity to study single cell clones in MDS and determine the sequence of genetic events and the influence of rigosertib on these events along with clinical outcomes.

- In December 2018, Onconova applied to the FDA for a Special Protocol Assessment (SPA) for a Phase 3 trial of oral rigosertib in combination with azacitidine for treatment of first-line higher-risk MDS patients. The Company expects completion of the FDA's SPA decision before the end of 2019.

- Results from the Phase 2 trial were reported in December 2018 in an oral presentation at the 2018 American Society of Hematology (ASH) meeting and updated at the 2019 European Hematology Association Meeting.

Additional Progress for Rigosertib and Pipeline Products

- ON 123300, an investigational first-in-class dual inhibitor of CDK4/6 + ARK5 with the potential to treat a variety of cancers, continues to make progress toward clinical development in the U.S. and China in partnership with HanX. HanX has conducted toxicology studies to support an IND filing in the U.S.

- The collaboration with the National Cancer Institute as well as one with a Center of Excellence in Juvenile Myelomonocytic Leukemia, or JMML, for preclinical studies of rigosertib for treatment of pediatric cancer associated RASopathies are ongoing.

- Onconova continues to participate in important medical and investment conferences. During the second quarter, presentations related to rigosertib development and clinical trials were made at:

    - 15th Annual International Symposium on MDS/Copenhagen
    - Acute Leukemia Forum/Shanghai
    - BIO International Forum/Philadelphia
    - European Hematology Association/Amsterdam

Upcoming 2019 conferences include:

- RAS-Targeted Drug Discovery Summit (Boston, September 17-19)
- Brazilian Association of Hematology, Hemotherapy and Cellular Therapy Congress (Rio de Janeiro, November 6-9)
- The American Society of Hematology (ASH) Conference in (Orlando, December 7-10)

Second Quarter 2019 Financial Results

Cash and cash equivalents as of June 30, 2019, totaled $5.9 million compared to $17.0 million at December 31, 2018. The Company believes that cash and cash equivalents at June 30, 2019, along with additional funds to be received from the HanX license in the third quarter, will be sufficient to fund ongoing trials and operations late into the fourth quarter of 2019. The Company was notified by Nasdaq on July 26 that Nasdaq has accepted the Company's plan to regain compliance with the stockholders' equity listing requirement by November 18, 2019.

Net loss was $3.6 million for the quarter ended June 30, 2019, compared to $4.3 million for the second quarter ended June 30, 2018. Research and development expenses were $3.9 million for the quarter ended June 30, 2019, and $4.1 million for the comparable period in 2018. General and administrative expenses were $1.8 million for the quarter ended June 30, 2019, and $2.1 million for the comparable period in 2018.

Conference Call and Webcast Information

The Company will host a conference call today, August 14, 2019, at 9 a.m. Eastern Time, to provide a corporate update and discuss second quarter 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 90141175. The call will also be webcast live. Please click here to access the webcast. A replay will be available following the live webcast.

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 Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company discovering and developing novel small molecule drug candidates to treat cancer, with a 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. 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 visit http://www.onconova.com.

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication demonstrated 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 clinic with oral and IV rigosertib, including single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in first-line 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 **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 HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an 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. An interim analysis in early 2018 demonstrated a promising survival signal in the intent-to-treat population as reviewed by the Independent Data Monitoring Committee. The 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 study 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 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 higher-risk MDS (HR-MDS), after failure of hypomethylating agent, or HMA, therapy.

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 combination therapy modalities. To date, over 400 patients have been studied with the oral formulation of rigosertib. 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 preliminary efficacy and safety data was presented at The American Society of Hematology Annual Meeting in December 2018. A Special Protocol Assessment for a pivotal Phase 3 study design is under review by the FDA.

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, the need for additional financing, the success and timing of Onconova's clinical trials and regulatory approval of protocols, our collaborations, 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.

General Contact

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

TABLES FOLLOW

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	June 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 5,882	$ 16,970
Receivables	1,714	35
Prepaid expenses and other current assets	833	760
Total current assets	8,429	17,765
Property and equipment, net	1	9
Other non-current assets	150	149
Total assets	$ 8,580	$ 17,923
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,750	$ 4,039
Accrued expenses and other current liabilities	3,770	4,173
Deferred revenue	226	226
Total current liabilities	8,746	8,438
Warrant liability	571	176
Deferred revenue, non-current	3,809	3,922
Total liabilities	13,126	12,536
Stockholders' (deficit) equity:		
Preferred stock	—	—
Common stock	60	57
Additional paid in capital	388,465	387,238
Accumulated other comprehensive income	(14)	(12)
Accumulated deficit	(393,057)	(381,896)
Total Onconova Therapeutics Inc., stockholders' (deficit) equity	(4,546)	5,387
Non-controlling interest	—	—
Total stockholders' (deficit) equity	(4,546)	5,387
Total liabilities and stockholders' equity	$ 8,580	$ 17,923

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations *(unaudited)*

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six months months ended June 30,	
	2019	2018	2019	2018
Revenue	$ 2,022	$ 485	$ 2,090	$ 1,049
Operating expenses:				
General and administrative	1,760	2,054	4,994	3,943
Research and development	3,895	4,070	7,969	8,647
Total operating expenses	5,655	6,124	12,963	12,590
Loss from operations	(3,633)	(5,639)	(10,873)	(11,541)
Change in fair value of warrant liability	32	513	(395)	1,325
Other income, net	40	805	107	805
Net loss	(3,561)	(4,321)	(11,161)	(9,411)
Net loss attributable to non-controlling interest	—	(163)	—	(163)
Net loss attributable to Onconova Therapeutics, Inc	$ (3,561)	$ (4,484)	$ (11,161)	$ (9,574)
Net loss per share of common stock, basic and diluted	$ (0.60)	$ (1.10)	$ (1.89)	$ (3.76)
Basic and diluted weighted average shares outstanding	5,948,471	4,070,405	5,919,446	2,548,281