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 15, 2017**

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))

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 15, 2017, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and six months ended June 30, 2017, 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 15, 2017.

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 15, 2017

Onconova Therapeutics, Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by the Company dated August 15, 2017.

Exhibit 99.1

Onconova Therapeutics, Inc. Reports Recent Business Highlights and Second Quarter 2017 Financial Results

NEWTOWN, Pa., August 15, 2017 (GLOBE NEWSWIRE) — Onconova Therapeutics, Inc. (NASDAQ:ONTX), 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), today provided a corporate update and reported financial results for the second quarter ended June 30, 2017.

"We are advancing IV rigosertib in a late stage clinical trial for patients with unmet medical needs in MDS. Our Phase 3 INSPIRE trial with IV rigosertib is enrolling globally and the next milestone of interim analysis is anticipated in the fourth quarter," said Dr. Ramesh Kumar, President and Chief Executive Officer.

"After consulting with regulators in the US and Europe following Phase 1/2 data with oral rigosertib in combination with azacitidine, we are designing a Phase 3 trial in first-line higher risk MDS patients for submission under a Special Protocol Assessment," continued Dr. Kumar. "We also believe there is interest for our pediatric RASopathies rare disease collaborative program from the National Cancer Institute, academia, and patient advocacy which we find extremely gratifying."

INSPIRE Trial of IV Rigosertib in 2nd Line Higher-risk (HR) MDS

Interim Analysis

- The INSPIRE protocol allows for a pre-planned interim analysis. This analysis will be triggered after reaching 88 events (deaths). Although it is difficult to accurately forecast the timing of this milestone, based on when we expect to finalize our statistical analysis plan, enrollment statistics, and our expectations for survival of the trial population, we anticipate this to occur in Q4-2017.

- The Statistical Analysis Plan (SAP) for interim and top-line analysis is under review by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Trial Progress

- As of July 31, 72 sites in 16 countries across four continents have enrolled patients for this study. Countries and trial sites were carefully chosen to ensure availability of appropriate patients meeting stringent eligibility criteria. Since these criteria were purposely designed to be narrow and selective, extensive eligibility verification and trial site education are integral to our plan.

- Enrollment for the trial has slowed recently, which could be related to seasonality. The Company is taking proactive measures to increase enrollment including the addition of trial sites in three new countries and changes within its CRO group. Should enrollment not return to desired levels, full enrollment may be delayed by several months.

Oral Rigosertib in Combination with Azacitidine for 1st-line HR-MDS

Pivotal Phase 3 Trial Protocol

- Following receipt of the final minutes from our End-of-Phase 2 discussion with the FDA in 3Q-2016, a Scientific Advice process was initiated with the EMA and was completed in July. Based on this feedback, we are designing a Phase 3 protocol for a 1:1 randomized controlled trial of oral rigosertib + azacitidine compared with azacitidine + placebo in first-line patients with HR-MDS. We plan to initiate the FDA Special Protocol Assessment (SPA) process following completion of the ongoing Expansion Phase 1/2 trial.

- Initiation of the trial, which is planned to be conducted globally, requires additional financing.

Expansion of Phase 1/2 Trial of Oral Rigosertib in Combination with Azacitidine

- This expansion phase is designed to enroll up to approximately 40 patients. The key objectives are to optimize dosing and schedule of administration of oral rigosertib in combination with azacitidine.

- After appropriate amendments were filed with the regulatory agencies, we started the expansion phase of this trial. Four sites are now open in the U.S. and we plan to activate additional sites in US, Europe and Australia. The first patient was enrolled in April.

Other Programs for Future Development or Partnership and Presentations

New Collaborative Program in "RASopathies": Rare Disease in Children

- Based on new mechanism of action data published last year (*Cell*, 2016), we initiated a collaborative development program focusing on a group of rare diseases, RASopathies, which share a well-defined molecular basis in expression or defects involving Ras Effector Pathways. Pediatric "RASopathies" is a subset of these rare diseases, and we are embarking on a multifaceted collaborative program involving patient advocacy, government, and academic organizations. In addition to drug supply and expertise, we believe we can contribute organizational oversight to this project.

- We expect to execute a formal Collaborative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the National Institutes of Health.

- Investigators in the NCI have designed a protocol for a trial in pediatric patients with certain RASopathies complicated by cancer.

- Since our focus area of MDS is related to a pediatric rare disease, Juvenile Myelomonocytic Leukemia (JMML), we are exploring collaboration with an academic group focused on development of novel therapeutics for these children. Initial non-clinical studies in Stem Cells and animal models may influence the design of an appropriate clinical study in this patient population.

- In July 2017, we presented a summary of our targeted approach to a symposium organized by Rasopathiesnet.org, a patient advocacy organization. We are also sponsoring an educational

event (a "Key Opinion Leader" breakfast) in the fourth quarter to bring together disease area experts, patient advocacy groups and our knowledge, to draw attention to this unmet medical need and the potential for rigosertib in this quest.

Recent Presentations

- The Company presented a poster at the American Society of Clinical Oncology Annual Meeting on Monday, June 5th focusing on "Further Rationale for Rigosertib in a Second-line HR-MDS Setting." Bone marrow response was evaluated as a surrogate for survival in this trial of 64 patients who had failed hypomethylating agents. 22% of these patients achieved marrow complete response (mCR) and 47% of patients achieved disease stabilization.

- The Company contributed multiple presentations at the 22nd Congress of the European Hematology Association on June 24th. The presentations incorporated clinical and non-clinical data evaluating oral rigosertib plus azacitidine. The data presented demonstrated that the combination may overcome hypomethylating agent resistance, and also indicates that further study in acute myeloid leukemia is warranted. SymBio, Onconova's partner in Japan and Korea, presented Phase 1 safety data for intravenous rigosertib in Japanese patients with recurrent/relapsed or refractory Myelodysplastic Syndromes.

- Dr. Steven Fruchtman, Onconova's Chief Medical Officer, highlighted approaches for studying rigosertib in RAS-associated cancers on Sunday, July 30th at the 5th International RASopathies Symposium organized by RASopathies Network. The primary focus of this presentation was JMML, which is incurable without an allogenic hematopoietic stem cell transplant.

Proprietary Preclinical Next Generation CDK4/6 + ARK5 Inhibitor

- New CDK inhibitors are making an impact for patients with breast and lung cancers. These orally available agents have potential utilities in a broad range of solid tumors and we believe will become an integral part of cancer therapy in the future.

- Our CDK inhibitor is differentiated from other agents on the market (such as Palbociclib, Ribociclib and Abemaciclib) or in development (such as the compounds being developed by G1 Therapeutics) by its dual inhibition of CDK4/6 + ARK5. We continue to carry out preclinical research to enhance the data package for this compound in an attempt to seek partners for co-development of this novel new chemical entity.

Second-Quarter Business Highlight:

- On April 26, 2017, Onconova closed a public offering resulting in gross proceeds of approximately $5.2 million, before underwriting discounts, commissions and estimated offering costs. New institutional investors, existing investors, as well as Directors and Management of the Company participated in the round. On May 17, 2017, the underwriters exercised their

option to purchase an additional 363,580 shares, which resulted in additional gross proceeds of $0.8 million.

Second-Quarter Financial Results:

- Cash, cash equivalents, and marketable securities as of June 30, 2017 totaled $15.0 million, compared to $21.4 million as of December 31, 2016.
- Total net revenue was $0.3 million for the second quarter of 2017 and $0.5 million for the six months ended June 30, 2017, compared to $2.2 million and $3.7 million, respectively, for the comparable periods in 2016.
- Research and development expenses were $4.6 million for the second quarter of 2017 and $9.5 million for the six months ended June 30, 2017, compared to $5.6 million and $11.4 million, respectively, for the comparable periods in 2016.
- General and administrative expenses were $1.8 million for the second quarter of 2017 and $3.9 million for the six months ended June 30, 2017, compared to $2.1 million and $5.3 million, respectively, for the comparable periods in 2016.

The Company will host a conference call on August 15th at 9:00 a.m. Eastern Time to provide a corporate update and discuss second quarter financial results. 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: 48705257.

The call will also be webcast live at: http://investor.onconova.com/events.cfm

A replay will be available at that link until November 15, 2017.

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 the Company believes 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. The advanced clinical trial with the Company's lead compound, rigosertib, is aimed at what the Company believes are unmet medical needs of patients with MDS. For more information, please visit http://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 the randomized Phase 3 international INSPIRE trial for patients with higher-risk (HR) MDS, after failure of hypomethylating agent, or HMA, therapy. This formulation is intended for patients with advanced disease, to provide long duration of exposure, and to ensure dosing under a controlled setting.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **I**V **R**igos**E**rtib, or INSPIRE, is based on guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the analysis 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 the National Comprehensive Cancer Network (NCCN) Guidelines. The trial will enroll approximately 225 patients 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 and an interim analysis is anticipated. 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 also supports 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 future events or Onconova Therapeutics, Inc.'s future operations, clinical development of Onconova's product candidates and presentation of data with respect thereto, regulatory approvals, expectations regarding the sufficiency of Onconova's cash and other resources to fund operating expenses and capital expenditures, Onconova's anticipated milestones and future expectations and plans and prospects. 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.

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.

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

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 14,989	$ 21,400
Receivables	233	31
Prepaid expenses and other current assets	761	1,638
Total current assets	15,983	23,069
Property and equipment, net	105	152
Other non-current assets	12	12
Total assets	$ 16,100	$ 23,233
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,681	$ 5,323
Accrued expenses and other current liabilities	3,728	4,382
Deferred revenue	455	455
Total current liabilities	9,864	10,160
Warrant liability	1,476	3,401
Deferred revenue, non-current	4,318	4,545
Total liabilities	15,658	18,106
Stockholders' equity:		
Preferred stock	—	—
Common stock	99	68
Additional paid in capital	348,672	342,484
Accumulated other comprehensive income	(10)	(31)
Accumulated deficit	(349,149)	(338,224)
Total Onconova Therapeutics Inc. stockholders' (deficit) equity	(388)	4,297
Non-controlling interest	830	830
Total stockholders' equity	442	5,127
Total liabilities and stockholders' equity	$ 16,100	$ 23,233

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ 324	$ 2,248	$ 534	$ 3,722
Operating expenses:				
General and administrative	1,779	2,083	3,895	5,254
Research and development	4,614	5,564	9,500	11,386
Total operating expenses	6,393	7,647	13,395	16,640
Loss from operations	(6,069)	(5,399)	(12,861)	(12,918)
Change in fair value of warrant liability	3,474	8	1,925	279
Other income, net	11	10	11	18
Net loss	$ (2,584)	$ (5,381)	$ (10,925)	$ (12,621)
Net loss per share of common stock, basic and diluted	$ (0.29)	$ (1.96)	$ (1.38)	$ (4.61)
Basic and diluted weighted average shares outstanding	8,999,125	2,740,211	7,891,408	2,735,901