

ONCONOVA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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**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 15, 2017**

Onconova Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

001-36020
(Commission
File Number)

22-3627252
(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 May 15, 2017, Onconova Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 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 May 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: May 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 May 15, 2017.

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

NEWTOWN, Pa., May 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, today provided a corporate update and reported financial results for the first quarter ended March 31, 2017.

“We had a productive start to 2017, advancing the Phase 3 trial for our lead clinical candidate and securing funding to support ongoing clinical stage trials for patients with Myelodysplastic Syndromes (MDS). The presentation of positive data on two preclinical candidates representing potentially novel approaches for the treatment of Solid Tumors and Acute Myeloid Leukemia, Multiple Myeloma, and Lymphoma has resulted in increased interest from partners, and underscores the depth of our pipeline,” said Dr. Ramesh Kumar, President and Chief Executive Officer.

“The INSPIRE Phase 3 trial for our lead clinical candidate, rigosertib, for the second-line treatment of patients with higher-risk (HR) MDS continues to advance as planned, with interim analysis and key enrollment milestones ahead. While we design our global Phase 3 trial of oral rigosertib in combination with azacitidine for first line HR MDS patients, we are expanding our Phase 2 combination trial to obtain additional efficacy and tolerability data across a larger number of trial sites. We plan to seek a Special Protocol Assessment in the United States after first obtaining Scientific Advice from the European regulatory authorities during the third quarter of this year. Thus, we are well-positioned for multiple key milestones as we seek to address the underserved needs of patients with MDS.”

Enrollment Progressing for INSPIRE Trial of IV Rigosertib in 2nd Line HR-MDS

INSPIRE Trial Update

- 172 trial sites selected globally
 - 18 countries with regulatory and IRB/ethics approvals
 - Australia, Austria, Belgium, Canada, Croatia, Czech Republic, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Poland, Spain, Sweden, UK & USA
 - Sites expected to initiate in May or June in Switzerland
 - Clinical trial applications are underway for 3 countries (Estonia, Hungary and Russia)
 - 163 sites opened to date (44 North America, 86 ROW, 33 Japan)
 - As of April 30, 60 sites in 14 countries have enrolled patients
 - First patients in Belgium, Ireland, Israel and Italy were enrolled in March or April
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INSPIRE Trial Statistical Analysis Plan (SAP)

- The SAP will provide clarity to the upcoming interim analysis as well as the top-line analysis of the INSPIRE trial. This document is currently under review by the Food and Drug Administration (FDA) and European Medicines Agency (EMA). We expect a response in Q2-2017.

Second Data Monitoring Committee (DMC) Review Completed

- In this pre-planned safety analysis of data from enrolled patients in the INSPIRE trial, the DMC recommended that the study continue as planned.

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

Phase 3 Trial Protocol

- A synopsis of this Phase 3 trial has been completed and a briefing book has been submitted to the EMA for Scientific Advice.
- A protocol for a Phase 3 trial for first-line patients with HR-MDS is being designed according to the trial parameters discussed during the end of Phase 2 meeting with the FDA in late 2016.
- The Company expects to submit the protocol to the FDA for a Special Protocol Assessment during the third quarter of this year.

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

- The two key objectives of this study are to obtain additional data on efficacy and tolerability of the combination regimen by continuing dose exploration and Quality of Life assessment in the new cohorts.
- We anticipate opening more than 10 sites in this extension of the Phase 2 trial, including all three sites that participated in the original study. We plan to enroll up to 40 new patients in this study.
- The first two patients have been enrolled in this expansion study.

Recent Data Presentation

- The Company presented clinical data at the 14th International Symposium on Myelodysplastic Syndromes taking place May 3-6th in Valencia, Spain, with the Company's collaborators from the Mount Sinai School of Medicine and the Cleveland Clinic.
 - The oral presentation of data from the Phase 2 combination trial highlighted the duration of response in patients with Complete Remission and presented a case study of a hypomethylating agent (HMA) refractory patient who had responded positively to the combination therapy for more than two years. In a poster presentation, a new prognostic tool being developed at the Cleveland Clinic was applied to conduct a retrospective analysis of ONTIME trial data to highlight the heterogeneity of the enrolled patients. The INSPIRE trial eligibility is designed to permit enrollment of a more homogeneous patient population.
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Rare Disease Program in “Rasopathies”

- Based on new mechanism of action data published last year, Onconova is initiating a collaborative development program focusing on a group of rare diseases with a well-defined molecular basis in defects in the Ras Effector Pathways.
- The Company is developing preclinical and clinical collaborative programs with the National Institutes of Health (NIH)/ National Cancer Institute (NCI), academic investigators and Patient Advocacy Groups.
- The NIH/ NCI scientists have developed a broad ranging protocol for pediatric rasopathies. Onconova expects to execute a cooperative research and development agreement with the NIH/NCI for a clinical trial with rigosertib in these indications.
- Another therapeutic focus will be Juvenile Myelomonocytic Leukemia, a well-described rasopathy affecting children, which is incurable without an allogenic hematopoietic stem cell transplant.
- Further details of this program will be presented in a Key Opinion Leader session expected to be held during Q3-2017.

Proprietary Preclinical New Chemical Entities show Positive Results

- Positive preclinical data was announced at the American Association for Cancer Research (AACR) annual meeting, for ON 123300, a first-in-class dual inhibitor of CDK4/6 + ARK5, and for ON 150030, a novel Type 1 inhibitor of FLT3 and Src pathways. The meeting took place April 1-5 in Washington, DC.
- In a preclinical Rb+ve xenograft model for breast cancer, ON 123300 activity was shown to be similar to Palbociclib (Pfizer’s Ibrance®). Moreover, based on the same preclinical model, the new molecule may have the potential advantage of reduced neutropenia when compared to Palbociclib. Whereas both compounds resulted in decreased RBC and platelet counts in this preclinical model system, Palbociclib was found to have a more prominent and statistically significant ($P < 0.05$) inhibitory effect on neutrophil counts when compared to ON 123300. A full copy of the above AACR poster can be accessed here.
- Preclinical studies at the Icahn School of Medicine at Mount Sinai revealed that ON 150030 inhibited the growth of MV4-11 cells harboring the FLT3-ITD mutation (GI50: 10nM). Western blot analysis demonstrated that MAPK and PI3K/AKT pathways in these cells was inhibited with an increasing dose of ON 150030.

Recent Business Highlights:

- 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 this round. In May 2017, the underwriters exercised their option to purchase an additional 363,580 shares, which is expected to close on May 17, 2017 and will result in additional gross proceeds of \$0.8 million.
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First-Quarter Financial Results:

- Cash and cash equivalents as of March 31, 2017, totaled \$15.4 million, compared to \$21.4 million as of December 31, 2016. This excludes the proceeds from the financing completed in April 2017, in which the Company raised approximately \$5.2 million before underwriting discounts and commissions and estimated offering costs in a public offering of common stock through Laidlaw & Company (UK) Ltd. This also excludes the proceeds from the exercise of the underwriter's over-allotment option which is expected to raise an additional \$0.8 million before deducting underwriting discounts and commissions and estimated offering costs. Onconova believes that its current cash and cash equivalents will be sufficient to fund its ongoing trials and operations to the end of 2017.
- Net revenue was \$0.2 million for the first quarter of 2017, compared to \$1.5 million in the year ago quarter.
- Research and development expenses were \$4.9 million in the first quarter of 2017, compared to \$5.8 million a year ago.
- General and administrative expenses were \$2.1 million for the first quarter of 2017, compared to \$3.2 million for the year-ago period.
- The first quarter net loss was \$8.3 million, compared to a net loss of \$7.2 million in the first quarter of 2016.

The Company will host a conference call on May 15th at 9:00 a.m. Eastern Time to provide a corporate update and discuss first 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: 10612725.

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

A replay will be available at that link until August 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 we believe 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, while causing minimal damage to normal 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 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 MDS, after failure of hypomethylating agent, or HMA, therapy. This formulation is intended for patients with advanced disease, provides long duration of exposure, and ensures 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 findings 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 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 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)

	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,389	\$ 21,400
Receivables	126	31
Prepaid expenses and other current assets	898	1,638
Total current assets	16,413	23,069
Property and equipment, net	129	152
Other non-current assets	12	12
Total assets	<u>\$ 16,554</u>	<u>\$ 23,233</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,407	\$ 5,323
Accrued expenses and other current liabilities	4,021	4,382
Deferred revenue	455	455
Total current liabilities	9,883	10,160
Warrant liability	4,950	3,401
Deferred revenue, non-current	4,432	4,545
Total liabilities	<u>19,265</u>	<u>18,106</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	68	68
Additional paid in capital	342,982	342,484
Accumulated other comprehensive income	(26)	(31)
Accumulated deficit	(346,565)	(338,224)
Total Onconova Therapeutics Inc. stockholders' equity	(3,541)	4,297
Non-controlling interest	830	830
Total stockholders' (deficit) equity	<u>(2,711)</u>	<u>5,127</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 16,554</u>	<u>\$ 23,233</u>

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

	Three Months Ended March 31,	
	2017	2016
Revenue	\$ 210	\$ 1,474
Operating expenses:		
General and administrative	2,116	3,172
Research and development	4,886	5,822
Total operating expenses	<u>7,002</u>	<u>8,994</u>
Loss from operations	(6,792)	(7,520)
Change in fair value of warrant liability	(1,549)	271
Other income, net	—	9
Net loss	<u>\$ (8,341)</u>	<u>\$ (7,240)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (1.23)</u>	<u>\$ (2.65)</u>
Basic and diluted weighted average shares outstanding	<u>6,771,383</u>	<u>2,731,590</u>