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 8, 2018**

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 x

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. o

Item 2.02. Results of Operations and Financial Condition

On March 8, 2018, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 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 March 8, 2018.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by the Company dated March 8, 2018.

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: March 8, 2018

Onconova Therapeutics, Inc.

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

Onconova Therapeutics, Inc. Reports Business Highlights and Full Year 2017 Financial Results

NEWTOWN, Pa., March 8, 2018 (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 full year ended December 31, 2017.

“The recently completed year was a pivotal period for rigosertib development programs in MDS. We achieved important goals across our full pipeline, highlighted by the recently announced promising interim analysis and the advancement of the INSPIRE pivotal trial for rigosertib, our lead Phase 3 clinical candidate. With no FDA approved therapies available for patients with higher-risk MDS who are refractory to hypomethylating agents, Onconova has taken a leadership position in this indication. Looking ahead, we now expect topline analysis to be concurrent with enrollment completion, which can be achieved in the first half of 2019,” said Dr. Ramesh Kumar, President and Chief Executive Officer.

“We also announced three important collaborations in recent months. Regional licensing of our pre-IND stage next generation CDK 4/6 inhibitor for Greater China which we believe advnaces this program on the IND track and towards clinical data in 2019. Our collaboration with the National Cancer Institute for clinical development of rigosertib in children suffering from incurable inherited diseases (RASopathies) could provide Onconova with the opportunity to establish a rare disease development program. Finally, our licensing agreement for rigosertib in Latin America further expands the global commercial footprint of rigosertib, and is in addition to our existing partnership in Japan and Korea. Execution of these transactions we believe indicates the ability to leverage our late stage and pipeline assets to finance multiple programs. Based on the progress achieved in our oral rigosertib-azacitidine combination Phase 2 program in front-line MDS indications, we expect to secure additional collaborations and regional partnerships to help support a pivotal Phase 3 trial for oral rigosertib.”

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

Interim Analysis (IA)

- On January 17, 2018, Onconova announced that it is moving forward with its Phase 3 INSPIRE pivotal trial following the interim analysis and the Data Monitoring Committee’s (DMC) recommendation, together with unanimous approval by the Executive Committee overseeing this trial. The DMC recommended continuation of the trial with a one-time expansion in enrollment, using a pre-planned sample size re-estimation, consistent with the Statistical Analysis Plan.
- The expanded INSPIRE study will increase enrollment by adding 135 patients to the original target to reach a total enrollment of 360 patients.
- At the topline analysis of the INSPIRE trial, the primary endpoint of overall survival will be analyzed in both the ITT population and the Very High Risk (VHR) subgroup.
- In the INSPIRE trial enrollment so far, the predefined subgroup of VHR patients constitutes greater than 70% of patients enrolled to date.
- The Company remains blinded to the interim analysis results.

Trial Progress

- The INSPIRE study is open in more than 170 sites in 22 countries across four continents.
- More than half of the expanded study is now enrolled.
- The Company is planning to add sites in Europe and new territories, including in Latin America, in concert with our new partner Pint Pharma (“Pint”).
- The INSPIRE trial was designed with stringent selection criteria so as to identify a more homogenous MDS patient population. Accordingly, extensive eligibility verification and trial site education are integral to the Company’s plan.

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

Pivotal Phase 3 Trial Protocol

- Phase 2 Expansion Trial is expected be fully enrolled this month with the addition of more than 40 patients.
- Onconova plans to present initial data from this study at a scientific conference in 2018, highlighting the results of dose selection and optimization of the combination regimen.
- On March 2, 2018, Onconova presented data relating to the mechanism of action of rigosertib in combination with azacitidine at the AACR Special Conference. The results suggested potential novel clinical strategies to improve outcomes for patients with higher-risk MDS and reversal of resistance to treatment with epigenetic therapies.

Progress in Business Development around Rigosertib and Pipeline Products

Onconova and Pint Pharmaceutical Announce Licensing Agreement for Rigosertib in Latin America

- On March 5, 2018, Onconova and Pint announced that they had entered into a Latin American licensing agreement for rigosertib. Pint is a private, European-based pharmaceutical company focused on the development, registration and commercialization of specialty-based treatments for the Latin American market.
- Under the terms of the agreement, Pint will make an investment in Onconova totaling up to $2.5 million by purchasing shares at a premium to market. In addition, Pint will make potential additional regulatory, development and sales-based milestone payments to Onconova of up to $42.75 million and pay double digit tiered royalties on net sales in Latin America.

Rigosertib Collaboration for Pediatric RASopathies

- On January 4, 2018, Onconova announced that it had entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes of Health. Under the terms of the CRADA, the NCI will conduct research, including preclinical

laboratory studies and a clinical trial, on rigosertib in pediatric cancer associated RASopathies. The RASopathies are a group of rare diseases which share a well-defined molecular basis in expression or defects involving Ras Effector Pathways.

License and Collaborative Development Agreement with HanX Biopharmaceuticals for ON 123300

- On December 19, 2017, Onconova announced the signing of a license and collaboration agreement with HanX Biopharmaceuticals, Inc., a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in China. ON 123300 is a first-in-class dual inhibitor of CDK4/6 + ARK5, which is currently in advanced pre-clinical development. This compound has the potential to overcome the limitations of current generation CDK 4/6 inhibitors.
- Under the terms of the agreement, Onconova will receive an upfront payment, and is eligible to receive potential regulatory and commercial milestone payments, as well as royalties on Chinese sales. HanX will provide all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval. The Companies also intend for these studies to comply with US Food and Drug Administration (FDA) standards. Accordingly, such studies may be used by Onconova for an IND filing with the FDA. Onconova will maintain global rights outside of China.

Pre-clinical Stage CDK4/6 + ARK5 Inhibitor Program

Following signing of the collaboration agreement with HanX, Onconova initiated a pre-IND process with the U.S. Food and Drug Administration (FDA).

Presentations of Data

Rigosertib in MDS at the ASH 2017 Meeting

- Onconova delivered two poster presentations highlighting drug activity and the mechanism of action of rigosertib in MDS during the 59th American Society of Hematology Annual Meeting and Exposition in Atlanta in December, 2017.
- Among the highlights of the presentation were: Oral rigosertib as a single agent demonstrated activity in a Phase 2 trial for lower-risk MDS; 32% of 62 evaluable patients, and 44% of patients receiving optimal dosing, achieved transfusion independence; and new data on the molecular basis of the combination therapy with rigosertib and azacitidine in epigenetic studies in patient derived stem cells.

Full Year 2017 Financial Results:

- Cash and cash equivalents as of December 31, 2017, totaled $4.0 million, compared to $21.4 million as of December 31, 2016. Subsequently, on February 12, 2018, Onconova announced the closing of a $10 million underwritten public offering of 9,947,500 shares of common stock or common stock equivalents and warrants to purchase an aggregate of 994,750 shares of Onconova's Series A convertible preferred stock, including the exercise in full of the underwriter's option to purchase additional securities, at the public offering price of $1.01 per share and accompanying Preferred Stock Warrant. Onconova also issued to the underwriter a preferred stock warrant to purchase 49,737.5 shares of Series A convertible preferred stock. Based on the Company's cash burn for 2017 and its current projections, Onconova expects that cash and cash equivalents will be sufficient to fund ongoing trials and operations into the third quarter of 2018.

- Net loss was $24.1 million for the year ended December 31, 2017, compared to $19.7 million for the year ended December 31, 2016, primarily due to the lack of collaboration cost sharing revenue in the 2017 period and a smaller change in fair value of warrant liability in the 2017 period.

- Research and development expenses were $19.1 million for the year ended December 31, 2017, and $20.1 million for the comparable period in 2016.

- General and administrative expenses were $7.4 million for the year ended December 31, 2017, and $9.2 million for comparable period in 2016.

The Company will host a conference call on March 8th at 9:00 a.m. Eastern Time to provide a corporate update and discuss fourth quarter and full-year 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: 2947108.

The call will also be webcast live. Please click here to access the webcast.

A replay will be available at this link until June 29, 2018.

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. 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 a randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **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 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. Following interim analysis in early 2018, the independent Data Monitoring Committee recommended

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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 treatment 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 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 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 Onconova Therapeutics, Inc.’s expectations regarding the INSPIRE Trial, existing and future collaborations and partnerships, and other product candidates. 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.

General Contact

http://www.onconova.com/contact/

Investor Relations Contact

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ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	December 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 4,024	$ 21,450
Receivables	59	31
Prepaid expenses and other current assets	820	1,588
Total current assets	4,903	23,069
Property and equipment, net	64	152
Other non-current assets	12	12
Total assets	$ 4,979	$ 23,233
Liabilities and stockholders’ equity		
Current liabilities:		

Accounts payable	$ 6,186	$ 5,323
Accrued expenses and other current liabilities	3,335	4,382
Deferred revenue	455	455
Total current liabilities	9,976	10,160
Warrant liability	1,773	3,401
Deferred revenue, non-current	4,091	4,545
Total liabilities	15,840	18,106
Stockholders' (deficit) equity:		
Preferred stock	—	—
Common stock	108	68
Additional paid in capital	350,514	342,484
Accumulated other comprehensive income	3	(31)
Accumulated deficit	(362,316)	(338,224)
Total Onconova Therapeutics Inc. stockholders' (deficit) equity	(11,691)	4,297
Non-controlling interest	830	830
Total stockholders' (deficit) equity	(10,861)	5,127
Total liabilities and stockholders' (deficit) equity	$ 4,979	$ 23,233

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2017 (unaudited)	2016
Revenue	$ 787	$ 5,546
Operating expenses:		
General and administrative	7,405	9,178
Research and development	19,119	20,071
Total operating expenses	26,524	29,249
Loss from operations	(25,737)	(23,703)
Change in fair value of warrant liability	1,628	3,988
Other income, net	30	62
Net loss before income taxes	(24,079)	(19,653)
Income taxes	13	14
Net loss	(24,092)	(19,667)
Net loss attributable to non-controlling interest	—	—
Net loss attributable to Onconova Therapeutics, Inc.	$ (24,092)	$ (19,667)
Net loss per share of common stock, basic and diluted	$ (2.68)	$ (4.44)
Basic and diluted weighted average shares outstanding	9,000,326	4,426,639