# 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, 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:

☐ 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, 2018, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2018, 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, 2018.

EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release issued by the Company dated May 15, 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: May 15, 2018

Onconova Therapeutics, Inc.

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

**Exhibit 99.1**

**Onconova Therapeutics, Inc. Reports Business Highlights and Financial Results for First Quarter 2018**

**NEWTOWN, Pa., May 15, 2018 — 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 first quarter of 2018 ended March 31, 2018.

"We have strengthened our balance sheet after completing a $28.75 million upsized underwritten public offering this month. Combined with the funds raised in February, we now have the resources necessary to advance our INSPIRE Phase 3 clinical trial of IV Rigosertib towards complete enrollment, which we expect in the first half of 2019," said Dr. Ramesh Kumar, President and Chief Executive Officer. "After enrollment of our expanded Phase 2 combination therapy trial and the advance of our CDK inhibitor preclinical program towards the clinic, we are well-positioned in our quest to serve the unmet needs of cancer patients."

**Recent Highlights**

- In May, we strengthened our balance sheet with a $28.75 million upsized underwritten public offering. This financing, combined with the $10.0 million offering completed in February, should permit the Company to advance its late stage programs in MDS to key milestones;
- We executed a licensing agreement with Pint Pharma to commercialize Rigosertib for treatment of Myelodysplastic Syndromes in Latin America;
- We presented promising Phase 2 data from the expansion study of oral Rigosertib and Azacitidine combination in patients with Myelodysplastic Syndromes at the 6th International Bone Marrow Failure Disease Symposium on March 26$^{th}$;
- We completed the Pre-IND consultation with the US Food and Drug Administration (FDA) regarding ON 123300, a dual ARK5+CDK4/6 inhibitor, in collaboration with our partner, HanX Biopharmaceuticals. This guidance will help advance our differentiated compound to the clinic;
- We presented data on our first-in-class dual inhibitor of CDK4/6 + ARK5 at the American Association for Cancer Research Annual Meeting 2018 on April 19$^{th}$.

**First Quarter 2018 Financial Results**

Cash and cash equivalents as of March 31, 2018, totaled $7.3 million, compared to $4.0 million as of December 31, 2017. This excludes the proceeds from the financing completed in May 2018, in which the Company raised net proceeds of approximately $25.6 million in a public offering, including the exercise in full of the underwriter's over-allotment option. Based on the Company's current projections, Onconova expects that cash and cash equivalents will be sufficient to fund ongoing trials and operations into the fourth quarter of 2019.

Net loss was $5.1 million for the first quarter ended March 31, 2018, compared to $8.3 million for the first quarter ended March 31, 2017, primarily due to a decrease in the fair value of warrant liability, and the recognition of revenue during the quarter from our license and collaborative development agreement with HanX Biopharmaceuticals. Research and development expenses were $4.6 million for the first quarter ended March 31, 2018, and $4.9 million for the comparable period in 2017. General and administrative expenses were $1.9 million for the first quarter ended March 31, 2018, and $2.1 million for comparable period in 2017.

The Company will host a conference call on Tuesday, May 15 at 9:00 a.m. Eastern Time to provide a corporate update and discuss first quarter 2018 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: 2573768. The call will also be webcast live. Please click here to access the webcast. A replay will be available at this link until August 15, 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 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:**

Mark Guerin
Onconova Therapeutics, Inc.
267-759-3680
http://www.onconova.com/contact/

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

| | March 31, 2018 (unaudited) | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 7,264 | $ 4,024 |
| Receivables | 477 | 59 |
| Prepaid expenses and other current assets | 814 | 820 |
| Total current assets | 8,555 | 4,903 |
| Property and equipment, net | 48 | 64 |
| Other non-current assets | 12 | 12 |
| Total assets | $ 8,615 | $ 4,979 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,034 | $ 6,186 |
| Accrued expenses and other current liabilities | 3,063 | 3,335 |
| Deferred revenue | 455 | 455 |
| Total current liabilities | 10,552 | 9,976 |
| Warrant liability | 961 | 1,773 |
| Deferred revenue, non-current | 3,977 | 4,091 |
| Total liabilities | 15,490 | 15,840 |
| | | |
| Stockholders' deficit: | | |
| Preferred stock | — | — |
| Common stock | 194 | 108 |
| Additional paid in capital | 359,496 | 350,514 |
| Accumulated other comprehensive income | 11 | 3 |
| Accumulated deficit | (367,406) | (362,316) |
| Total Onconova Therapeutics Inc., stockholders' deficit | (7,705) | (11,691) |
| Non-controlling interest | 830 | 830 |
| Total stockholders' deficit | (6,875) | (10,861) |
| Total liabilities and stockholders' deficit | $ 8,615 | $ 4,979 |

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

| | Three months ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (unaudited) | |
| Revenue | $ 564 | $ 210 |
| Operating expenses: | | |
| General and administrative | 1,889 | 2,116 |
| Research and development | 4,577 | 4,886 |
| Total operating expenses | 6,466 | 7,002 |
| Loss from operations | (5,902) | (6,792) |
| | | |
| Change in fair value of warrant liability | 812 | (1,549) |
| Net loss | (5,090) | (8,341) |
| Net loss attributable to non-controlling interest | — | — |
| Net loss attributable to Onconova Therapeutics, Inc. | $ (5,090) | $ (8,341) |
| | | |
| Net loss per share of common stock, basic and diluted | $ (0.34) | $ (1.23) |
| Basic and diluted weighted average shares outstanding | 15,138,663 | 6,771,383 |