# 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 11, 2021**

## 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 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

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act

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 |
| Warrants to purchase common stock | 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 March 11, 2021, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2020, 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.

| Exhibit No. | Exhibit |
|---|---|
| 99.1 | Press release issued by the Company dated March 11, 2020 |

**SIGNATURES**

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 11, 2021

Onconova Therapeutics, Inc.

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

**Exhibit 99.1**

# Onconova Therapeutics Reports Full Year 2020 Financial Results, Provides Business Update

*Conference call begins at 4:30 p.m. Eastern time today*

**NEWTOWN, Pa., March 11, 2021 (GLOBE NEWSWIRE) – Onconova Therapeutics, Inc. (NASDAQ: ONTX)** ("Onconova"), a clinical-stage biopharmaceutical company focused on discovering and developing novel therapies for patients with cancer, announces financial results for the twelve months ended December 31, 2020 and provides a business update.

Highlights of the fourth quarter of 2020 and recent weeks include:

- ON 123300, Onconova's proprietary multi-kinase inhibitor, received clearance from the U.S. Food and Drug Administration (FDA) to begin Phase 1 studies
- ON 123300 also received Institutional Review Board (IRB) approval at one U.S. clinical trial site
- The Phase 1 solid tumor study with ON 123300 in China is ongoing and continues to enroll patients
- Raised net proceeds of $35.2 million from two equity offerings; cash and cash equivalents as of February 28, 2021 were approximately $49.5 million
- An independent investigator-initiated study with oral rigosertib in combination with a PD-1 inhibitor in advanced KRAS mutated non-small cell lung cancer is ongoing
- A Special Meeting of Stockholders to consider changes to the capital structure of the Company will reconvene on April 1, 2021

**Management Commentary**

"The fourth quarter and recent weeks have been active and productive at Onconova as we continue to advance our lead product ON 123300 into the clinic," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "We submitted an Investigational New Drug application to the FDA for a Phase 1 study in advanced cancers including HR+/HER 2- metastatic breast cancer patients resistant to approved second-generation CDK 4/6 inhibitors. In December 2020, we received clearance from the FDA to begin the study, and have since received IRB approval at our first site. We expect the first patient to be enrolled in the second quarter of this year. Two further sites are in the study set-up process.

"This Phase 1 study will assess the safety, tolerability and pharmacokinetics of ON 123300 administered orally at increasing doses starting at 40 mg daily continuously.

"Our partner in China, HanX Pharmaceuticals, continues enrolling a similar patient population in a Phase 1 dose-escalation study with ON 123300 at two sites. The initial dose cohort has been completed and the second dose cohort is enrolling. We are pleased that ON 123300 appears to be well tolerated so far as no dose-limiting toxicities have been seen to date. The HanX study is dosing patients on a 21-day cycle. Collectively, the U.S. and China Phase 1 studies are expected to provide data regarding the safety profile of ON 123300 and potentially provide preliminary efficacy signals in patients with advanced cancer."

Commenting on ongoing investigator-sponsored studies with oral rigosertib, the company's RAS pathway inhibitor, Dr. Fruchtman added, "We are currently supporting investigator-initiated studies that are exploring the use of oral rigosertib for cancers driven by mutation of the RAS gene including a Phase 1 study in combination with a PD-1 inhibitor for patients with progressive K-RAS mutated non-small cell lung cancer. This study is open and continues to enroll patients, with the objectives to identify the recommended Phase 2 dose and to characterize the safety profile of the combination treatment. Results are expected in 2021.

"In addition, an investigator-initiated Phase 1b/2 study with oral rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa is open. A preclinical study is also evaluating oral rigosertib in clear cell renal carcinoma. We anticipate additional investigator-initiated studies in RAS-driven cancers in combination with PD-1 inhibitors, including in metastatic melanoma. Other than the cost of supplying oral rigosertib to the investigators, Onconova does not expect to incur significant expense for these studies," Dr. Fruchtman stated.

**Full Year Financial Results**

Cash and cash equivalents as of December 31, 2020 were $19.0 million, compared with $22.7 million as of December 31, 2019. Subsequent to the end of the quarter, the Company raised net proceeds of $35.2 million from two equity offerings with institutional investors. The Company expects that its cash and cash equivalents as of February 28, 2021 will be sufficient to fund ongoing clinical trials and business operations for more than eighteen months.

Research and development expenses were $16.9 million for 2020, compared with $15.5 million for 2019. The increase was primarily related to higher regulatory consulting fees and manufacturing costs related to clinical supply for ON 123300, partially offset by lower expenses for the oral rigosertib combination program and the Phase 3 INSPIRE study in the 2020 period.

General and administrative expenses were $8.3 million for 2020, consistent with 2019. Lower personnel and stock compensation expenses in 2020 due to personnel reductions in the 2019 period were offset by higher pre-commercialization, insurance, and corporate legal and stockholder meeting expenses in the 2020 period.

Net loss for 2020 was $25.2 million, or $0.14 per share on 174.0 million weighted average shares outstanding, compared with a loss of $21.5 million, or $1.49 per share for 2019 on 14.4 million weighted average shares outstanding.

**Conference Call and Webcast**

Onconova will host an investment community conference call today beginning at 4:30 p.m. Eastern time, during which management will discuss financial results for 2020, provide a business update and answer questions. Interested parties can participate by dialing (855) 428-5741 (domestic callers) or (210) 229-8823 (international callers) and using conference ID 3863774.

A live webcast of the conference call will be available in the Investors & Media section of the Company's website at www.onconova.com. A replay of the webcast will be available on the Onconova website for 90 days following the call.

**About Onconova Therapeutics, Inc.**

Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel therapies for patients with cancer. The Company has proprietary targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation.

Onconova’s novel, proprietary multi-kinase inhibitor ON 123300 is planned to begin a dose-escalation and expansion Phase 1 trial in the U.S. in 2Q21, and a dose-escalation and expansion Phase 1 trial is currently underway in China. Onconova’s product candidate oral rigosertib is currently in a dose-escalation and expansion Phase 1 investigator-initiated study targeting patients with KRAS+ lung adenocarcinoma in combination with nivolumab. In addition, Onconova continues to conduct preclinical work investigating rigosertib in COVID-19. For more information, please visit www.onconova.com.

**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’s expectations regarding the registered direct offering, its patents and clinical development plans including patient enrollment timelines and indications for its product candidates. 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 the success and timing of Onconova's clinical trials and regulatory agency and institutional review board approvals of protocols, Onconova’s ability to continue as a going concern, the need for additional financing, Onconova’s collaborations, market conditions 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.

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

**Investor Contact:**
LHA Investor Relations
Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

(Tables to follow)

**ONCONOVA THERAPEUTICS, INC.**

**Condensed Consolidated Balance Sheets**

*(in thousands)*

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| | *(unaudited)* | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 19,025 | $ 22,726 |
| Receivables | 37 | 98 |
| Prepaid expenses and other current assets | 722 | 650 |
| Total current assets | 19,784 | 23,474 |
| Property and equipment, net | 52 | 50 |
| Other non-current assets | 150 | 150 |
| Total assets | $ 19,986 | $ 23,674 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,833 | $ 4,271 |
| Accrued expenses and other current liabilities | 4,962 | 3,795 |
| Deferred revenue | 226 | 226 |
| Total current liabilities | 10,021 | 8,292 |
| Warrant liability | 321 | 113 |
| Deferred revenue, non-current | 3,469 | 3,695 |
| Total liabilities | 13,811 | 12,100 |
| | | |
| Stockholders' equity: | | |
| Preferred stock | - | - |
| Common stock | 1,859 | 1,112 |
| Additional paid in capital | 432,858 | 413,879 |
| Accumulated other comprehensive income (loss) | 14 | (18) |
| Accumulated deficit | (428,556) | (403,399) |
| Total stockholders' equity | 6,175 | 11,574 |
| Total liabilities and stockholders' equity | $ 19,986 | $ 23,674 |

**ONCONOVA THERAPEUTICS, INC.**

**Condensed Consolidated Statements of Operations *(unaudited)***

*(in thousands, except share and per share amounts)*

| | Year Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| | *(unaudited)* | |
| Revenue | $ 231 | $ 2,183 |
| Operating expenses: | | |
| General and administrative | 8,326 | 8,345 |
| Research and development | 16,898 | 15,537 |
| Total operating expenses | 25,224 | 23,882 |
| Loss from operations | (24,993) | (21,699) |
| | | |
| Change in fair value of warrant liability | (208) | 63 |
| Other income, net | 48 | 143 |
| Net loss before income taxes | (25,153) | (21,493) |
| Income tax expense | 4 | 10 |
| Net loss | (25,157) | (21,503) |
| | | |
| Net loss per share of common stock, basic and diluted | $ (0.14) | $ (1.49) |
| Basic and diluted weighted average shares outstanding | 174,035,872 | 14,384,476 |

# # #