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): **December 18, 2020**

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)) 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
Common Stock Warrants	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 ☐

Item 7.01. Regulation FD Disclosure.

On December 21, 2020, Onconova Therapeutics, Inc. ("Onconova" or the "Company") issued a press release announcing that it has received permission from the U.S. Food and Drug Administration ("FDA") for a Phase 1 study to proceed under an Investigational New Drug application that the Company submitted for its product candidate ON 123300. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information disclosed under this Item 7.01 (including Exhibit 99.1) is being furnished and 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 8.01. Other Events.

On December 18, 2020, Onconova received permission from the FDA for a Phase 1 study to proceed under an Investigational New Drug application that the Company submitted for its product candidate ON 123300. Following Institutional Review Board approval, the Company plans to begin a Phase 1 study of ON 123300 in the United States.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press release of Onconova Therapeutics, Inc. issued on December 21, 2020

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: December 21, 2020

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Announces FDA Permission for Study to Proceed Under its Investigational New Drug Application for Multi-kinase CDK4/6 Inhibitor ON 123300

Company affirms plans to begin enrollment of patients with HR+ HER2- metastatic breast cancer and other tumors in U.S. Phase 1 trial in the first half of 2021

NEWTOWN, Pa., Dec. 21, 2020 (GLOBE NEWSWIRE) -- **Onconova Therapeutics, Inc. (NASDAQ: ONTX),** a biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced receipt of U.S. Food and Drug Administration (FDA) permission for a Phase 1 study to proceed under the Company's Investigational New Drug application (IND) for ON 123300, a proprietary, differentiated, first-in-class multi-kinase inhibitor.

"We are grateful to receive this timely, favorable response from the FDA to initiate a Phase 1 trial with ON 123300," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "We are advancing the process to secure Institutional Review Board approval, and affirm our expectation that the first patient will be enrolled during the first half of 2021."

The Phase 1 trial will be conducted in the U.S. and will assess the safety, tolerability and pharmacokinetics of ON 123300 administered orally as monotherapy at increasing doses starting at 40 mg daily or higher for consecutive 28-day cycles. The trial will enroll patients with relapsed/refractory advanced cancer, including but not limited to patients with HR+ HER2- metastatic breast cancer with clinical resistance to approved second-generation CDK4/6 inhibitors. Once the dose escalation phase of the trial is completed and the recommended Phase 2 dose is established, additional HR+ HER2- postmenopausal metastatic breast cancer patients resistant to approved second-generation CDK4/6 inhibitors will be enrolled. Additional patient cohorts are under consideration, including but not limited to patients diagnosed with advanced colorectal cancer, and non-Hodgkin's lymphoma, in particular mantle cell lymphoma.

The design of this U.S. Phase 1 trial differs from the ongoing study with ON 123300 in China conducted by the Company's partner HanX Biopharmaceuticals, Inc., which is dosing patients daily for 21 days. The HanX trial has enrolled four patients to date, has opened the second dosing cohort and is expected to continue enrolling patients with advanced cancer at two sites until the recommended Phase 2 dose is identified. Notably, of the three currently approved CDK4/6 inhibitors, two are approved for dosing in 21-day cycles and one is approved for dosing in a 28-day cycle. All three are blockbuster drugs marketed in HR+ HER2– metastatic breast cancer by well-known pharmaceutical companies, and all of these approved therapies require concomitant treatment with an aromatase inhibitor.

"Based on its differentiated mechanism of action, we believe that ON 123300 presents an innovative approach to study advanced cancers including in HR+ HER2- metastatic breast cancer that is or has become resistant to commercial CDK4/6 inhibitors. Beyond metastatic breast cancer, we believe that ON 123300 may present a novel approach to treating other cancers including mantle cell lymphoma, multiple myeloma, advanced colorectal cancer and hepatocellular carcinoma, as well as inoperable glioblastoma based on preclinical studies suggesting ON 123300 crosses the blood-brain barrier," added Richard Woodman, M.D, Chief Medical Officer.

About ON 123300

Onconova's lead pipeline compound is the novel small molecule ON 123300, a proprietary, first-in-class multi-kinase inhibitor targeting tumor-driving kinases including CDK4/6 and ARK5. ON 123300 is reported to simultaneously inhibit both cell cycle and cellular energy metabolism through CDK4/6 and ARK5, respectively, and *in vitro* has been shown to be cytotoxic to cancer cells (killing the cancer cells). The current commercial CDK inhibitors are reported to be cytostatic (inhibiting the growth of cancer cells). With its differentiated mechanism of action, ON 123300 may present an innovative approach for treating solid tumors and hematologic malignancies that are refractory to or have become resistant to other CDK4/6 inhibitors. Based on experiments in preclinical models, ON 123300 exhibits single-agent cytotoxicity, and may have utility for certain types of cancers including breast cancer, non-Hodgkin's lymphoma including mantle cell lymphoma, multiple myeloma, colorectal cancer, hepatocellular carcinoma, and inoperable glioblastoma.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a biopharmaceutical company focused on discovering and developing novel products to treat 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 currently in a dose-escalation and expansion Phase 1 trial in China, and a dose-escalation and expansion Phase 1 trial is planned in the U.S. to commence in the first half of 2021. 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. Preclinical work with rigosertib in COVID-19 is ongoing as well. Although some preclinical experiments with rigosertib in cellular models demonstrated marked inhibition of SARS-CoV-2 replication, we do not anticipate conducting clinical trials with rigosertib in COVID-19 without securing additional funding. 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 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, 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.

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