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): **April 19, 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 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

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 7.01. Regulation FD Disclosure.

On April 19, 2018, Onconova Therapeutics, Inc. ("Onconova" or the "Company") issued a press release relating to ON 123300 as described in Item 8.01 below. 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 April 19, 2018, the Company issued a press release announcing an advance in pre-clinical development and the presentation of new data for investigational ON 123300, a novel dual inhibitor of CDK4/6 + ARK 5 with potential application across a variety of cancers.

CDK inhibitors have emerged as promising and potentially targeted large market cancer therapies. ON 123300 has the potential to overcome many of the limitations of current generation CDK4/6 inhibitors. Onconova believes that ON 123300 may act as a single agent, due to the unique targeting of ARK5, as well as CDK 4 and 6, making it potentially suitable for indications that may not be responsive to the current generation of CDK4/6 inhibitors.

Onconova and HanX Biopharmaceuticals, the Company's Greater China collaboration partner for ON 123300, recently completed the pre-Investigational New Drug ("pre-IND") consultation with the U.S. Food and Drug Administration ("FDA"). These discussions provided guidance for the manufacturing of ON 123300 and the pre-clinical development plan for the submission of an Investigational New Drug ("IND") application.

The data from preclinical studies demonstrates that there is a differential metabolism of ON 123300 in male versus female rodents. As a result, the drug exposure is almost 2-3 fold higher in female rats. Based upon preclinical animal liver microsome studies, this differential effect appears to be limited to rodents, and is not observed in preclinical studies with human liver microsomes. Based on the metabolism data from other species, relevant species have been selected along with the dosing strategy to be implemented in GLP toxicological studies to be conducted by HanX. As a part of the pre-clinical development program, Onconova and HanX announced a collaborative program in December 2017, wherein the remaining IND enabling studies will be funded by and conducted by HanX.

Onconova previously reported that ON 123300 was found to be as active as Palbociclib (Pfizer's Ibrance®) in a preclinical Rb + ve xenograft model. Moreover, the molecule may have the potential advantage of reduced neutropenia when compared to Palbociclib based upon this model.

Forward Looking Statements

Some of the statements in this report 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 the Company's expectations regarding the clinical studies, therapeutic effects and other aspects of ON 123300 and the Company's collaboration with HanX Biopharmaceuticals. Although the Company 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. The Company 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 the Company'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 the Company's clinical trials and regulatory approval of protocols, and those discussed under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q.

Any forward-looking statements contained in this report speak only as of its date. The Company undertakes no obligation to update any forward-looking statements contained in this report to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press release dated April 19, 2018

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated April 19, 2018

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: April 19, 2018

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Presents Data on Dual Inhibitor of CDK4/6 + ARK5 at American Association for Cancer Research 2018 Annual Meeting

- Onconova receives productive pre-IND guidance from FDA regarding first-in-class compound ON 123300
- Preclinical data reveals differential metabolism of ON 123300 in male versus female rodents, with implications for development of dosing strategy
- Development program is in collaboration with HanX Biopharmaceuticals, which has commercialization rights in Greater China
- Next major milestone is IND filing by Onconova in the US and HanX in China

NEWTOWN, Pa., April 19, 2018 (GLOBE NEWSWIRE) — Onconova Therapeutics, Inc. (NASDAQ:ONTX), a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, announced an advance in pre-clinical development and the presentation of new data for investigational ON 123300, a novel dual inhibitor of CDK4/6 + ARK 5 with potential application across a variety of cancers.

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along with the dosing strategy to be implemented in GLP toxicological studies to be conducted by HanX. As a part of the pre-clinical development program, Onconova and HanX announced a collaborative program in December 2017, wherein the remaining IND enabling studies will be funded by and conducted by HanX.

Onconova previously reported that ON 123300 was found to be as active as Palbociclib (Pfizer's Ibrance®) in a preclinical Rb + ve xenograft model. Moreover, the molecule may have the potential advantage of reduced neutropenia when compared to Palbociclib based upon this model.

Ramesh Kumar, President and CEO of Onconova, commented, "At the end of March, we received pre-IND guidance from the FDA, which provides a path towards filing an IND and then starting clinical trials. Our partner, HanX, has initiated GMP manufacturing and will be initiating GLP pre-clinical studies based on the guidance provided by the FDA, and we look forward to advancing ON 123300 into clinical development."

Faming Zhang, Ph.D., founder and Chairman of HanX, commented, "We are pleased to have completed the process chemistry and have initiated GMP manufacturing for ON 123300. GLP toxicology studies are planned and we will be undertaking additional preclinical studies to enhance the profile of this novel compound. In collaboration with Onconova, our goal is to simultaneously file the IND in the USA and China, as soon as possible. Once an IND is in place, HanX plans to initiate Phase 1 studies in China and also participate in more advanced global clinical trials."

A copy of the presentation is available by visiting the Scientific Presentations section of Onconova's website.

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 may be important in cancer cells. Onconova has three clinical stage product candidates and additional pre-clinical programs. Advanced clinical trials with the Company's lead compound, rigosertib, are aimed at what the Company believes are the unmet medical needs of patients with MDS. For more information, please visit http://www.onconova.com.

About HanX Biopharmaceuticals

HanX Biopharmaceuticals is an oncology specialty company with an innovative pipeline targeting PD1, VEGFR, OX40 in clinical and pre-clinical stages. The company has a strong management team with cross-border experience and advisors with expertise in drug discovery, regulatory, and GMP manufacturing.

About CDK Inhibitors:

A key feature of cancer cells is their ability to rapidly multiply. CDK inhibitors are thought to disrupt this process by blocking the activity of enzymes known as CDKs. In particular, CDK4 and CDK6 are considered potential anticancer drug targets, due to their role regulating cell cycle progression at the G1 restriction point. CDK inhibitors have the potential to treat one of the most common types of breast cancer known as hormone receptor-positive metastatic breast cancer, in which the cancer cells express hormone receptors.

ON 123300 was found to be as active as Palbociclib (Pfizer's Ibrance®) in a preclinical Rb + ve xenograft model. Moreover, based upon this model, the molecule may have the potential advantage of reduced neutropenia when compared to Palbociclib. Both compounds decreased RBC and platelet counts, however in this model system, Palbociclib had a more prominent and statistically significant ($P \leq 0.05$) inhibitory effect on neutrophil counts when compared to ON 123300 (30.70 ± 3.55 vs. 45.10 ± 2.04).

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General Contact

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

Investor Relations Contact

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