Onconova Therapeutics, Inc.
Form 8-K
April 19, 2018

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:

o Written communications pursuant to Rule 425 under the Securities Act

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

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

o 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 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 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, approxim 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