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 10, 2019**

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. ☐

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

Item 1.01. Entry into a Material Definitive Agreement

License and Collaboration Agreement

On May 10, 2019 (the "Effective Date"), Onconova Therapeutics, Inc. (the "Company") entered into a License and Collaboration Agreement (the "License Agreement") with HanX Biopharmaceuticals, Inc. ("HanX"). Under the terms of the License Agreement, the Company granted HanX an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how to develop and commercialize any pharmaceutical product (the "Product") containing rigosertib in all uses of rigosertib or the Product in humans therapeutics uses (the "Field") in the People's Republic of China, Hong Kong, Macau and Taiwan (the "Territory"). The Company retains the right to develop and commercialize pharmaceutical products containing rigosertib worldwide except for (i) in the Field in the Territory (ii) for Latin America, for which Pint Pharma acquired rights to commercialize in March 2018 and (iii) for Japan and Korea, for which SymBio acquired rights to develop and commercialize in July 2011. The parties have also agreed to negotiate in good faith a supply and quality agreement under which the Company will supply HanX with rigosertib and the Product and, subject to certain conditions, HanX also has the right to manufacture and supply rigosertib and Product for use and sale in the Territory, either by itself or through its affiliates or third party contract manufacturers.

HanX has agreed to make an upfront payment of $2,000,000 in cash and upfront equity investments of approximately $2,000,000 in the Company's common stock as described below, and will set aside $2,000,000 or equivalent local currency funds dedicated to research and development expense funding for the Product in the Territory. In addition, the Company is eligible to receive up to $45.5 million in regulatory, development and sales-based milestone payments as well as tiered royalties up to double digits based on net aggregate net sales in the Territory.

The License Agreement is subject to customary closing conditions. The License Agreement also contains customary provisions for termination by either party in the event of breach of the License Agreement by the other party, subject to a cure period, or bankruptcy of the other party. In the event the full upfront payment and the full upfront equity investments are not received by the Company or its designee within 60 days from the Effective Date, the License Agreement and all rights and licenses granted to HanX thereunder will automatically terminate, unless otherwise expressly waived in writing by the Company. HanX may terminate the License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. The Securities Purchase Agreements (defined below) will terminate upon the termination of the License Agreement.

Securities Purchase Agreements

In connection with the License Agreement, on May 10, 2019, the Company entered into a Securities Purchase Agreement with each of HanX and Abundant New Investments Ltd. ("Abundant"), an affiliate of HanX (each, a "Securities Purchase Agreement" and together, the "Securities Purchase Agreements").

- Under the HanX Securities Purchase Agreement, HanX has agreed to purchase 207,040 shares of the Company's common stock at a purchase price of $4.83 per share for a total purchase price of $1,000,003.20, which purchase will close (the "HanX Closing") no later than 60 days from the Effective Date, provided that, among other conditions, HanX has received the necessary approvals of, and registrations and filings with, the applicable governmental authorities of the People's Republic of China, in connection with the outbound direct investment by HanX in the Company and related currency exchange from Chinese *renminbi* into the United States dollars (such approvals, the "ODI Approvals"), and has completed the requisite currency conversion.

- Under the Abundant Securities Purchase Agreement, Abundant has agreed to: (i) purchase 103,520 shares of the Company's common stock at a purchase price of $4.83 per share for a total purchase price of $500,001.60 within two trading days of the Effective Date (the "Abundant Initial Closing"); and (ii) purchase 103,520 shares of the Company's common stock at a purchase price of $4.83 per share for a total purchase price of $500,001.60, which purchase will close (the "Abundant Subsequent Closing") no later than 60 days after the Abundant Initial Closing, provided that, among

other conditions, Abundant has received the ODI Approvals and completed the requisite currency conversion.

HanX and Abundant have agreed that the shares they have agreed to purchase under their respective Securities Purchase Agreement will be subject to lock-up restrictions for one year from the date of the HanX Closing and the Abundant Initial Closing, respectively, (each, a "Strategic Lock-Up Period"), and certain additional lock-up provisions as applicable.

HanX and Abundant are entitled to registration rights if they hold Registrable Securities (as defined in the Securities Purchase Agreement) upon the expiration of their respective Strategic Lock-Up Period, and the Company has agreed to use its reasonable best efforts to register such Registrable Securities on a registration statement on Form S-3 (or another appropriate form of registration statement if the Company is not eligible to use Form S-3), to cause such registration statement be declared effective by the Securities and Exchange Commission, and to maintain the effectiveness of such registration statement until HanX or Abundant as applicable no longer holds any Registrable Securities.

The foregoing description of the License Agreement and the Securities Purchase Agreements (the "Agreements") does not purport to be complete and is qualified in its entirety by the Agreements, copies of which the Company intends to file as exhibits to Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2019.

Item 8.01. Other Events.

On May 13, 2019, the Company issued a press release with respect to entering into the Agreements described under Item 1.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press release dated May 13, 2019

EXHIBIT INDEX

Exhibit No.	Exhibit
99.1	Press release dated May 13, 2019

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: May 16, 2019

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Announces License Agreement with HanX Biopharmaceuticals to Develop and Commercialize Rigosertib in Greater China

- Onconova to Receive $4 Million Upfront, including $2 Million Fee and $2 Million for Onconova Shares Purchased at a Premium, Plus up to $45.5 Million in Regulatory and Sales Milestones for Rigosertib in Greater China
- HanX to Dedicate $2 Million in Local Currency to Invest in Greater China Rigosertib Clinical Development Over the Next 24 Months
- Greater China Clinical Sites to Contribute to Current Global Phase 3 INSPIRE Study, Future Phase 3 Oral Rigosertib and Azacitidine Combination Study, and Future Lung Cancer Combination Studies Pursuant to a Joint Development Plan
- Onconova to Present Rigosertib Data and Pivotal Clinical Trials at Acute Leukemia Forum in Shanghai on May 31, 2019

NEWTOWN, Pa., May 13, 2019 — Onconova Therapeutics, Inc. (NASDAQ:ONTX), a Phase 3-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with an initial focus on myelodysplastic syndromes (MDS), today announced that it has entered into a license agreement for the Greater China territory with HanX Biopharmaceuticals, Inc. (HanX), a China-based pharmaceutical company focused on the development, registration, and commercialization of novel oncology products in China, to develop and commercialize rigosertib, a novel and targeted anti-cancer compound currently in a Phase 3 study for the treatment of higher-risk MDS (HR-MDS).

Under the terms of the agreement, Onconova has granted to HanX (i) an exclusive license to develop and commercialize rigosertib in Greater China and (ii) a non-exclusive license to manufacture rigosertib in Greater China. In exchange for these rights, HanX will make upfront payments totaling $6 million, $4 million of which are cash payments to Onconova, including a $2 million fee and an investment totaling $2 million in shares purchased at a premium to market. In addition, HanX will also place $2 million in escrow in local currency for rigosertib clinical development expenses in Greater China. Onconova could receive up to $45.5 million in regulatory, development. and sales-based milestone payments and tiered royalties up to double digits on net sales in Greater China. Onconova will initially supply the finished product for sale in the licensed territories. HanX will also support Onconova's clinical trial initiatives in the territory

"We are excited about our expanded collaboration with HanX, which now includes our lead investigational drug candidate, rigosertib, currently being studied in higher-risk MDS patients," said Steven M. Fruchtman, M.D., President and Chief Executive Officer. "We have now partnered with HanX for the development of rigosertib in Greater China, in addition to our continued collaboration on the development of ON 123300, our novel CDK4/6 and ARK5 inhibitor. We plan for patients from China to be included in Onconova's INSPIRE trial, and this additional source will support the goal of completing accrual to INSPIRE in the second half of 2019. In addition, we expect this agreement will broaden the exploration of additional indications for rigosertib, such as lung cancer. We look forward to presenting our data on rigosertib for the first time in China at the Acute Leukemia Forum being held in Shanghai on May 31, 2019."

Faming Zhang, Ph.D., Founder and Chairman of HanX, commented, "Our license agreement with Onconova for rigosertib is our second collaboration with Onconova following the IND enabling co-development of a novel CDK4/6 and ARK5 inhibitor program. Approximately 25-30 percent of all cancers involve a mutation of the Ras gene family. Rigosertib represents a novel mechanism of action to attenuate Ras signaling pathway and thus has the potential to affect a variety of cancers. Our pre-clinical testing shows that rigosertib acts synergistically in combination with HX-008, our PD-1 antibody which is now in phase II/III clinical trials in China, as well as being studied in solid tumor animal models. In collaboration with Onconova, our goal is to join the INSPIRE trial and the planned combination study of oral rigosertib with azacitidine for patients in Greater China with first line higher-risk MDS and also to initiate a proof-of-concept clinical study of the combination of rigosertib with our

PD-1 inhibitor in NSCLC with Ras mutations."

Rigosertib is currently being evaluated in the global, pivotal Phase 3 INSPIRE clinical trial in patients who have failed or relapsed after receiving currently approved therapeutic options, with a goal of full accrual in the second half of 2019. Rigosertib is also being evaluated in an expanded Phase 2 combination study with azacitidine in HR-MDS patients. Onconova has a research collaboration agreement with the National Cancer Institute to study rigosertib in rare pediatric Ras driven cancers. Rigosertib has been granted orphan drug designation for MDS in the United States and Europe. Onconova is partnered for rigosertib with SymBio Pharmaceuticals for Japan and Korea and with Pint Pharma for Latin America.

About HanX Biopharmaceuticals, Inc.

HanX Biopharmaceuticals, Inc. is an oncology specialty company with an innovative pipeline targeting PD-1, VEGFR, OX-40 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 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 an initial focus on Myelodysplastic Syndromes (MDS). Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule, 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 Myelodysplastic Syndromes

Myelodysplastic syndromes (MDS) are conditions that can occur when the blood-forming cells in the bone marrow become dysfunctional and thus produce an inadequate number of circulating blood cells. It is frequently associated with the presence of blasts or leukemic cells in the marrow. This leads to low numbers of one or more types of circulating blood cells, and to the need for blood transfusions. In MDS, some of the cells in the bone marrow are abnormal (dysplastic) and may have genetic abnormalities associated with them. Different cell types can be affected, although the most common finding in MDS is a shortage of red blood cells (anemia). Patients with higher-risk MDS may progress to the development of acute leukemia.

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication demonstrated rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinic with oral and IV rigosertib, including single agent IV rigosertib in second-line high-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in first-line high-risk MDS patients (Phase 2). Patents covering oral and injectable rigosertib have been issued in the U.S. and are expected to provide coverage until at least 2037.

About IV Rigosertib

The intravenous form of rigosertib has been studied in Phase 1, 2, and 3 clinical trials involving more than 1000 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with high-risk MDS (HR-MDS), after failure of hypomethylating agent, or HMA, therapy.

About the INSPIRE Phase 3 Clinical Trial

The **IN**ternational **S**tudy of **P**hase 3 **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. INSPIRE is a global 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 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. An interim analysis in early 2018 demonstrated a promising survival signal in the intent-to-treat population as reviewed by the Independent Data Monitoring Committee. The 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 study 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 combination therapy modalities. To date, over 400 patients have been studied with the oral formulation of rigosertib. Combination therapy of oral rigosertib with azacitidine, the standard of care in HR-MDS, has also been studied. 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 efficacy and safety data was presented at The American Society of Hematology Annual Meeting in December 2018. A pivotal Phase 3 study design is under review by the FDA, and the Special Protocol Assessment is expected to conclude in the 1H of 2019.

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 and health authority approval in combination with an aromatase inhibitor 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 commercially approved CDK 4 and 6 inhibitors but with extra anti-tumor metastasis activity in a preclinical Rb + ve xenograft model. Moreover, the molecule may have the potential advantage of reduced neutropenia in preclinical models.

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 expectations regarding its products, its collaboration with HanX, the INSPIRE Trial and Onconova's other development plans. 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 Onconova's ability to continue as a going concern, the need for additional financing, 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

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