

**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 2, 2018**

Onconova Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

001-36020
(Commission
File Number)

22-3627252
(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 1.01. Entry into a Material Definitive Agreement

License, Development and Commercialization Agreement

On March 2, 2018, Onconova Therapeutics, Inc. (the "Company") entered into a License, Development and Commercialization Agreement (the "License Agreement") with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint"). Under the terms of the License Agreement, the Company granted Pint 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 (the "Field") in Latin America countries (the "Territory," including Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba,

Dominican Republic, Ecuador, El Salvador, French Guiana, British Guiana, Suriname, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela). The Company retains the right to develop and commercialize pharmaceutical products containing rigosertib worldwide except for the sale of the Product in the Field in the Territory.

Pint has agreed to make an upfront equity investment and a subsequent equity investment in the Company's common stock as described under "Securities Purchase Agreement" below. In addition, the Company could receive up to \$42.75 million in additional regulatory, development and sales-based milestone payments as well as tiered, double digit royalties based on net aggregate net sales in the Territory. Pint also has agreed to purchase rigosertib and the Product exclusively from the Company in accordance with a supply and quality agreement between the parties.

Pint may terminate the License Agreement in whole (but not in part) at any time upon 45 days' prior written notice. 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.

Securities Purchase Agreement

In connection with the License Agreement, on March 2, 2018, the Company and Pint also entered into a Securities Purchase Agreement (the "Securities Purchase Agreement"), under which Pint has agreed to make an upfront equity investment. Closing of the upfront equity investment (the "Initial Closing") will be the later of April 1, 2018 and the date on which the Company files its charter amendment (the "Charter Amendment") to increase its authorized shares of common stock with the Delaware Secretary of State. Pursuant to these terms, Pint will purchase shares at a premium to the average of the volume weighted average price of common stock for the ten consecutive trading days ended March 2, 2018 at the Initial Closing. In the event that the Initial Closing does not occur by May 1, 2018, Pint will pay the Company the share purchase premium (the "Initial Closing Premium"), and the Company will sell to Pint shares of common stock without any purchase price premium when the Company has sufficient authorized shares on or before December 31, 2018. If the Initial Closing does not occur and by the close of business on December 31, 2018 the Company has not filed the Charter Amendment with the Secretary of State of the State of Delaware, the Securities Purchase Agreement will terminate. So long as Pint has paid the Initial Closing Premium, the License Agreement will not terminate due to Pint's failure to purchase shares in the upfront equity investment.

In addition, when the FDA approves a New Drug Application (the "NDA") for the Product, Pint will reimburse the Company for certain research and development expenses. Half of the reimbursement amount will be paid in cash, the other half of the amount will be by an equity investment at a premium to the average of the volume weighted average price of common stock for the ten consecutive trading days ended on the day the FDA approves the NDA. In the event the Securities Purchase Agreement is terminated due to nonoccurrence of the Initial Closing and the Company not filing the Charter Amendment by December 31, 2018 as described above, Pint will instead pay the Company a share purchase premium (the "Securities Purchase Half Premium"), based on the average of the daily volume weighted average price of common stock for ten consecutive trading days ending on the date the NDA is approved by the FDA, multiplied by the Securities Purchase Half Number of Shares, subject to certain conditions. So long as Pint has paid the Securities Purchase Half

2

Premium, the License Agreement will not terminate due to Pint's failure to purchase shares in connection with the FDA's approval of the NDA.

Pint has agreed that the shares it purchases under the Securities Purchase Agreement will be subject to lock-up restrictions for one year from the date of the Initial Closing or, if Pint pays the Initial Closing Premium, the date of such payment (the "Strategic Lock-Up Period"), and certain additional lock-up provisions as applicable.

Pint is entitled to registration rights if it holds Registrable Securities (as defined in the Securities Purchase Agreement) upon the expiration of the 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 Pint no longer holds any Registrable Securities.

Until Pint no longer holds any Registrable Securities, Pint also has the right to participate in any equity issuance by the Company in a private placement to institutional investors which includes at least one institutional investor that is not an affiliate of the Company. Subject to certain notice requirements, if Pint decides to participate, the Company will allow Pint to participate up to Pint's pro rata share of beneficial ownership of the Company's outstanding common stock on the same terms, conditions and price as with other investors.

The foregoing description of the License Agreement and the Securities Purchase Agreement (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 March 31, 2018.

Item 8.01. Other Events.

On March 5, 2018, 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

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Press release dated March 5, 2018

3

Onconova Therapeutics Announces License Agreement with Pint Pharma to Commercialize Rigosertib for Treatment of Myelodysplastic Syndromes in Latin America

Pint Pharma to Make Upfront Investment in Onconova
Onconova also Eligible to Receive up to \$42.75 Million in Regulatory and Sales Milestones

NEWTOWN, PA, MARCH 5, 2018 — Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with a primary focus on myelodysplastic syndromes (MDS), today announced that they have entered into a license agreement with Pint Pharma GmbH to commercialize rigosertib, a novel and targeted anti-cancer compound currently in a Phase 3 study for the treatment of MDS, a group of rare hematologic malignancies. Pint Pharma is a European-based pharmaceutical company focused on the development, registration and commercialization of specialty-based treatments for the Latin American market.

Under the terms of the agreement, Onconova has granted to Pint Pharma an exclusive license to commercialize rigosertib in Latin America. In exchange for these rights, Pint will make investment totaling up to \$2.5 million by purchasing shares at a premium to market. In addition, Pint Pharma will make additional regulatory, development and sales-based milestone payments to Onconova of up to \$42.75 million and pay double digit tiered royalties on net sales in Latin America. Onconova will supply the finished product for sale in the licensed territories. Pint Pharma will also support Onconova's clinical trial initiatives in the territory.

"Following the recently announced promising interim analysis of our Phase 3 INSPIRE trial, we remain dedicated to advancing IV rigosertib towards commercialization in order to address the needs of MDS patients who fail hypomethylating agents (HMAs). Since HMAs are used globally, we are seeking regional partnerships to help prepare for the commercialization of rigosertib worldwide. We are delighted to partner with Pint Pharma, which has a wide footprint in South and Central America, and view this license agreement as further validation of the potential of rigosertib for the treatment of MDS. We also look forward to working with the clinicians and experts at Pint Pharma to advance clinical trials for IV and oral rigosertib in important centers in their territory," said Dr. Ramesh Kumar, President and CEO of Onconova Therapeutics, Inc.

"We are excited about the opportunity to provide this therapy to patients in our region; we hope that rigosertib will become a reality in clinical oncological practice and deliver a new option to patients and specialists," said David Munoz, Chief Executive Officer of Pint Pharma. "Rigosertib is highly complementary to our comprehensive hematology oncology portfolio, and will further strengthen our mission to enable the Latin American population with life-altering conditions to live better lives by providing early and efficient access to innovative technologies."

Rigosertib is currently being evaluated in a Phase 3 INSPIRE clinical trial in patients who have failed or relapsed after receiving current therapeutic options, with top-line data expected in 2019. Rigosertib is also being evaluated in an expanded Phase 2 combination study with Azacitidine in MDS patients. Onconova recently signed a research collaboration agreement with the National Cancer Institute to study rigosertib in rare pediatric diseases. Rigosertib has been granted orphan drug designation for MDS in the United States and Europe. Onconova is partnered with Symbio Pharmaceuticals, Tokyo, for commercialization of rigosertib in Japan and Korea.

About Pint Pharma

PINT PHARMA INTERNATIONAL SA is a company registered under Swiss laws, having its registered office at Route de Chenaux 9, 1091 Bourg-en-Levaux, Switzerland, and is devoted to the development, registration, and commercialization of specialty based treatments. Pint Pharma benefits from leaders with extensive experience in the pharmaceutical sector and who are based strategically throughout Latin America and

Europe. Pint Pharma has a long track record of developing strong relationships with global pharmaceutical and healthcare companies. Pint Pharma strives to be the first Pan-Latin American provider of innovative and high value-added treatments within Rare Diseases, Specialty Care, and Oncology.

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 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 IV Rigosertib

The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trials involving more than 800 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy.

About INSPIRE

The **IN**ternational Study of **Phase III IV Rigosertib**, or INSPIRE, was finalized following guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a 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 the first 9 months or 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. Following interim analysis in early 2018, the independent Data Monitoring 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 treatment 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 many combination therapy modalities. To date, 368 patients have been treated with the oral formulation of rigosertib. Initial studies with single-agent oral rigosertib were conducted in hematological malignancies, lower-risk MDS, and solid tumors. Combination therapy of oral rigosertib with azacitidine and chemoradiotherapy has also been explored. 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 results were presented in 2016. This novel combination is the subject of an issued US patent with earliest expiration in 2028.

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 Therapeutics, Inc.'s expectations regarding the INSPIRE Trial and the transactions contemplated by the licensing agreement. 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.

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. 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 and current plans and future needs to scale back operations if adequate financing is not obtained, 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

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

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