# 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 11, 2016**

# 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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 2.02. Results of Operations and Financial Condition**

On May 11, 2016, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2016, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference. The information contained in this Form 8-K (including the exhibit hereto) 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 9.01. Financial Statements and Exhibits**

(d) Exhibits.

99.1 Press release issued by the Company dated May 11, 2016.

**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: May 11, 2016

Onconova Therapeutics, Inc.

By: /s/ MARK GUERIN
Name: Mark Guerin
Title: Vice President – Finance and Accounting and Chief Accounting Officer



EXHIBIT INDEX

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by the Company dated May 11, 2016. |

ONCONOVA
TARGETING CANCER | PROTECTING HEALTHY CELLS

**Onconova Therapeutics, Inc. Reports Recent Business Highlights and First Quarter 2016 Financial Results**

**NEWTOWN, PA, May 11, 2016** — Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today provided a corporate update and reported financial results for the first quarter ended March 31, 2016.

"We recently reported two important advances in the development of rigosertib for the unmet medical needs of patients with myelodysplastic syndromes (MDS). Foremost is the elucidation of the novel mechanism of action of rigosertib targeting the RAS pathway, recently published in *Cell*, and the release of detailed clinical data from our ONTIME Phase 3 study in *Lancet Oncology*. These peer-reviewed papers provide important validation of the mechanistic rationale for rigosertib as a novel treatment option for patients with MDS," said Ramesh Kumar, Ph.D., President and CEO of Onconova. "We are encouraged by the continued progress in the global Phase 3 INSPIRE trial which is now enrolling patients in the U.S. and Europe."

**Recent Business Highlights:**

**Progress in INSPIRE Pivotal Trial of Rigosertib in Higher-risk MDS (HR-MDS)**

- The global INSPIRE trial is now enrolling patients in the United States and Europe. As of May 3, 2016, 51 sites, including 13 in the U.S., are open and recruiting patients. This pivotal trial was initiated in 4Q2015.

- Results from Onconova's ONTIME trial were published in the top-tier, peer-reviewed journal, *Lancet Oncology*. The article, entitled, "Rigosertib versus best supportive care for patients with high-risk myelodysplastic syndromes after failure of hypomethylating drugs (ONTIME): a randomised, controlled, phase 3 trial," appeared in the March 8, 2016 online edition of the journal.

**Rigosertib Mechanism of Action**

- The unique RAS-targeted mechanism of action for rigosertib was published in the prestigious peer-reviewed experimental biology journal, *Cell*. The paper, entitled "A small molecule RAS-mimetic disrupts RAS association with effector proteins to block signaling," appeared in the April 21, 2016 edition of the journal.

**Proprietary NCE targeting ARK5 and CDK4/6**

- A presentation at the 2016 American Association of Cancer Research Annual meeting demonstrated the important differentiating features of ON 123300, Onconova's novel pre-clinical ARK5 and CDK4/6 targeted agent. Results indicated that the inhibitory activity of ON 123300 on ARK5 and CDK4/6 resulted in the activation of programmed cell death in colorectal cancer cells, while treatment with an approved CDK4/6 inhibitor merely resulted in cytostasis.

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**Upcoming Events**

- Enrollment of the first patient in the Phase 3 INSPIRE trial in Japan: 2Q2016

- Presentation of updated Phase 2 data from oral rigosertib combination trial in MDS: 2Q2016

- End of Phase 2 meeting with FDA to discuss data from oral rigosertib combination trial: 2H2016

**First Quarter 2016 Financial Results**

- Cash, cash equivalents, and marketable securities as of March 31, 2016 totaled $16.8 million, compared to $19.8 million as of December 31, 2015.
- Total net revenue was $1.5 million for the first quarter of 2016 compared to $0.1 million for the first quarter of 2015.
- Research and development expenses were $5.8 million for the first quarter of 2016 compared to $9.5 million for the first quarter of 2015.
- General and administrative expenses were $3.2 million for the first quarter of 2016 compared to $3.0 million for the first quarter of 2015.

**About Onconova Therapeutics, Inc.**

Onconova Therapeutics is a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer. Onconova's clinical and pre-clinical stage drug development candidates are derived from its extensive chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. In addition to rigosertib, the Company's most advanced product candidate, two other candidates are clinical stage, and several candidates are in pre-clinical stages. For more information, please visit http://www.onconova.com.

**About Rigosertib**

Rigosertib is a small molecule inhibitor of cellular signaling and acts as a RAS mimetic. These effects of rigosertib appear to be mediated by direct binding of the compound to the RAS-binding domain (RBD) found in many RAS effector proteins, including the Raf kinases and PI3K. The therapeutic focus for rigosertib is myelodysplastic syndromes (MDS), a group of bone marrow disorders characterized by ineffective formation of blood cells that often converts into acute myeloid leukemia (AML). Clinical trials for rigosertib are being conducted at leading institutions in the United States, Europe, and the Asia-Pacific region. Rigosertib is protected by issued patents (earliest expiry in 2026) and has been awarded Orphan Designation for MDS in the United States, Europe and Japan.

**About INSPIRE**

The **IN**ternational **S**tudy of **P**hase III **I**V **R**igos**E**rtib, or INSPIRE, is based on 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 nine months of 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. The trial will enroll approximately 225 patients 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 and an interim analysis is anticipated. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

**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, which involve risks and uncertainties. These statements relate to future events or Onconova Therapeutics, Inc.'s future operations, clinical development of Onconova's product candidates and presentation of data with respect thereto, regulatory approvals, expectations regarding the sufficiency of Onconova's cash and other resources to fund operating expenses and capital expenditures, Onconova's anticipated milestones and future expectations and plans and prospects. 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 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.

**ONCONOVA THERAPEUTICS, INC.**
**Condensed Consolidated Balance Sheets**
*(in thousands)*

| | March 31, 2016 (unaudited) | December 31, 2015 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,835 | $ 19,799 |
| Receivables | 1,368 | 1,504 |
| Prepaid expenses and other current assets | 1,203 | 1,882 |
| Total current assets | 19,406 | 23,185 |
| Property and equipment, net | 224 | 248 |
| Other non-current assets | 12 | 12 |
| Total assets | $ 19,642 | $ 23,445 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,296 | $ 3,421 |
| Accrued expenses and other current liabilities | 3,891 | 3,729 |
| Deferred revenue | 455 | 455 |
| Total current liabilities | 7,642 | 7,605 |
| Warrant liability | 295 | — |
| Deferred revenue, non-current | 4,886 | 5,000 |
| Total liabilities | 12,823 | 12,605 |
| | | |
| Stockholders' equity: | | |
| Preferred stock | — | — |
| Common stock | 274 | 255 |
| Additional paid in capital | 331,528 | 328,334 |
| Accumulated other comprehensive income | (16) | (22) |
| Accumulated deficit | (325,797) | (318,557) |
| Total Onconova Therapeutics Inc. stockholders' equity | 5,989 | 10,010 |
| Non-controlling interest | 830 | 830 |
| Total stockholders' equity | 6,819 | 10,840 |
| Total liabilities and stockholders' equity | $ 19,642 | $ 23,445 |

**ONCONOVA THERAPEUTICS, INC.**
**Condensed Consolidated Statements of Operations (unaudited)**
*(in thousands, except share and per share amounts)*

| | Three Months Ended March 31, | |
|---|---|---|
| | 2016 | 2015 |
| Revenue | $ 1,474 | $ 114 |
| Operating expenses: | | |
| General and administrative | 3,172 | 2,965 |
| Research and development | 5,822 | 9,498 |
| Total operating expenses | 8,994 | 12,463 |
| Loss from operations | (7,520) | (12,349) |
| | | |
| Change in fair value of warrant liability | 271 | — |
| Other income, net | 9 | (18) |
| Net loss | (7,240) | (12,367) |
| Net loss attributable to non-controlling interest | — | 24 |
| Net loss attributable to Onconova Therapeutics, Inc. | $ (7,240) | $ (12,343) |
| | | |
| Net loss per share of common stock, basic and diluted | $ (0.27) | $ (0.57) |
| Basic and diluted weighted average shares outstanding | 27,315,899 | 21,703,173 |

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