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): **August 14, 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 filing 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 (17 CFR 230.425)

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

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

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

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 2.02. Results of Operations and Financial Condition

On August 14, 2018, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and six months ended June 30, 2018, 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 August 14, 2018.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by the Company dated August 14, 2018.

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: August 14, 2018

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Reports Business Highlights and Financial Results for Second Quarter 2018

NEWTOWN, Pa., August 14, 2018 — Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3 stage biopharmaceutical company focused on developing rigosertib, a novel small molecule drug candidate to treat cancer, with a primary focus on Myelodysplastic Syndromes (MDS), today provided a corporate update and reported financial results for the second quarter of 2018, ended June 30, 2018. The Company ended the second quarter with $29.5 million in cash and cash equivalents, which included proceeds from an underwritten public offering completed in this quarter.

"We are pleased to have completed our public offering in May, which included new fundamental institutional biotech investors and broadened our shareholder base," commented Dr. Ramesh Kumar, Chief Executive Officer. "Combined with the financing we completed earlier this year and a licensing agreement in Latin America with Pint Pharma, we have significantly strengthened our balance sheet, providing a pathway to reaching anticipated key milestones in 2018 and 2019."

Steven M. Fruchtman, M.D., President, stated, "During the second quarter of 2018, we continued to make progress in our rigosertib clinical programs, including our IV rigosertib Phase 3 INSPIRE trial for 2nd-line higher-risk (HR) MDS patients. For this trial, we have opened new sites in countries already participating and added another country. We expect to complete the INSPIRE trial in the second half of 2019. After full enrollment of the Phase 2 oral rigosertib trial in combination with azacitidine in patients with either 1st-line HR-MDS or those with azacitidine-resistant disease, we are continuing to collect safety and efficacy data from this study. The combination trial with azacitidine is expected to advance to a pivotal Phase 3 trial for 1st-line HR-MDS patients in 2019, pending funding."

Upcoming Milestones (H2-2018 and 2019)

- Top-line data for the pivotal Phase 3 INSPIRE study, which will be available after 288 death events. Total enrollment is expected to be 360 randomized patients
- Presentation of updated efficacy and safety data from rigosertib/azacitidine combination Phase 2 studies in MDS at a medical meeting
- Regulatory submissions for the Phase 3 trial in MDS of the combination program
- Advance of RASopathy collaborative program to the clinic funded by NCI CRADA
- Investigator initiated studies for rigosertib indications beyond MDS
- IND for Dual CDK 4/6 + ARK5 inhibitor ON 123300 (IND studies funded by HanX Biopharmaceuticals)

Second Quarter Highlights

- In June, Steven M. Fruchtman, M.D., Chief Medical Officer and Senior Vice President, Research and Development, was promoted to President. During his three and a half year tenure, Dr. Fruchtman has been instrumental in advancing rigosertib to key data milestones. In his new role, Dr. Fruchtman is now providing leadership across the Company's entire product portfolio.

- In May, Onconova strengthened its balance sheet with the successful completion of a $28.75 million upsized underwritten public offering. This financing, combined with the $10.0 million offering completed in February 2018, enables the Company to advance its late-stage programs in MDS to key upcoming milestones; the start of the combination therapy pivotal studies in MDS will require additional funding and/or business development transactions.

- ON 123300, a first-in-class dual inhibitor of CDK4/6 + ARK5 has potential applications in a variety of cancers and is advancing toward clinical development in partnership with HanX Biopharmaceuticals, our Greater China collaborator. Following pre-IND consultations with the U.S. Food and Drug Administration, HanX has commenced manufacturing and toxicology studies to support filing of an IND in the U.S.

Second Quarter 2018 Financial Results

Cash and cash equivalents at June 30, 2018, totaled $29.5 million, compared to $4.0 million at December 31, 2017. This includes the net proceeds from the $28.75 million financing completed in May 2018, including the exercise in full of the underwriter's over-allotment option.

Net loss was $4.3 million for the second quarter ended June 30, 2018, compared to a net loss of $2.6 million for the second quarter ended June 30, 2017, primarily due to a $3.5 million gain on the change in warrant liability in the 2017 period compared to $0.5 million gain in the 2018 period. Research and development expenses were $4.1 million for the second quarter ended June 30, 2018, and $4.6 million for the comparable period in 2017. General and administrative expenses were $2.1 million for the second quarter ended June 30, 2018, and $1.8 million for comparable period in 2017.

Net loss was $9.4 million for the six months ended June 30, 2018, compared to a net loss of $10.9 million for the six months ended June 30, 2017, primarily due to $0.8 million of license fee revenue and $0.9 million less research and development expenses in the 2018 period.

The Company will host a conference call on Tuesday, August 14, at 9:00 a.m. Eastern Time to provide a corporate update and discuss second quarter 2018 financial results. Interested parties may access the call by dialing toll-free (855) 428-5741 from the U.S., or (210) 229-8823 internationally, and using conference ID: 5287175. The call will also be webcast live. Please click here to access the webcast. A replay will be available at this link until November 30, 2018.

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 **S**tudy of **P**hase III **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 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 U.S. 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 expectations regarding 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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ONCONOVA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 29,540	$ 4,024
Receivables	72	59
Prepaid expenses and other current assets	545	820
Total current assets	30,157	4,903
Property and equipment, net	34	64
Other non-current assets	12	12
Total assets	$ 30,203	$ 4,979
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,949	$ 6,186
Accrued expenses and other current liabilities	3,572	3,335
Deferred revenue	455	455
Total current liabilities	9,976	9,976
Warrant liability	448	1,773
Deferred revenue, non-current	3,864	4,091
Total liabilities	14,288	15,840
Stockholders' deficit:		
Preferred stock	—	—
Common stock	851	108
Additional paid in capital	385,966	350,514
Accumulated other comprehensive income	(5)	3
Accumulated deficit	(370,897)	(362,316)
Total Onconova Therapeutics Inc., stockholders' deficit	15,915	(11,691)
Non-controlling interest	—	830
Total stockholders' deficit	15,915	(10,861)
Total liabilities and stockholders' deficit	$ 30,203	$ 4,979

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	$ 485	$ 324	$ 1,049	$ 534
Operating expenses:				
General and administrative	2,054	1,779	3,943	3,895
Research and development	4,070	4,614	8,647	9,500
Total operating expenses	6,124	6,393	12,590	13,395
Income (loss) from operations	(5,639)	(6,069)	(11,541)	(12,861)
Gain on dissolution of GBO	693	—	693	—
Change in fair value of warrant liability	513	3,474	1,325	1,925
Other income, net	112	11	112	11
Net loss	(4,321)	(2,584)	(9,411)	(10,925)
Net loss attributable to non-controlling interest	(163)	—	(163)	—
Net loss applicable to common stockholders	$ (4,484)	$ (2,584)	$ (9,574)	$ (10,925)
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.29)	$ (0.25)	$ (1.38)
Basic and diluted weighted average shares outstanding	61,056,072	8,999,125	38,224,211	7,891,408