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 12, 2021**

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.)

12 Penns Trail
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))

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

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 o

Item 2.02 Results of Operations and Financial Condition.

On August 12, 2021, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2021, 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.

Exhibit No.	Exhibit
99.1	Press release issued by the Company dated August 12, 2021

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 12, 2021

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Reports Second Quarter 2021 Financial Results and Provides Business Update

Conference call and live webcast at 4:30 p.m. ET today

NEWTOWN, Pa., August 12, 2021 (GLOBE NEWSWIRE) – Onconova Therapeutics, Inc. (NASDAQ: ONTX) ("Onconova"), a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, today announced financial results for the three months ended June 30, 2021 and provided a business update.

Highlights for the second quarter of 2021 and subsequent weeks include:

- Enrollment in the first cohort of the Phase 1 solid tumor study of ON 123300 in the United States is complete with no dose limiting toxicities (DLT's) observed. The second cohort is currently open for enrollment.

- The Phase 1 solid tumor study of ON 123300 in China is ongoing with no DLT's observed to date. The study is currently enrolling the third dose cohort.

- The investigator-initiated Phase 1/2 study evaluating rigosertib in combination with the checkpoint inhibitor nivolumab in KRAS mutated non-small cell lung cancer (NSCLC) continues to progress. Initial data from the trial provide preliminary evidence of the anti-cancer activity of rigosertib-nivolumab combination therapy in patients who had previously failed all standard of care treatment, including checkpoint inhibition, and show that the maximum tolerated dose of rigosertib in combination with nivolumab was not yet determined in the three cohorts of the trial's dose-escalation phase.

- The first patient was dosed in an investigator-initiated Phase 2 study designed to assess the efficacy and safety of rigosertib in patients with recessive dystrophic epidermolysis bullosa (RDEB)-associated locally advanced/metastatic squamous cell carcinoma (SCC), an ultra-rare and invariably fatal condition.

- The Company strengthened its management team with the appointment of Mark Gelder, M.D., as Chief Medical Officer.

- Preclinical data published in the peer-reviewed journal *Molecular Cancer* show that rigosertib synergistically enhanced the efficacy of immune checkpoint blockade in a murine melanoma model via the induction of immune-mediated cancer cell death, supporting the continued clinical evaluation of rigosertib in combination with checkpoint inhibitors.

Management Commentary

"During the second quarter we achieved key clinical and corporate milestones," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "In our lead ON 123300 program, we initiated our U.S. Phase 1 study and recently opened enrollment to the second cohort, and our partner, HanX Biopharmaceuticals, is currently enrolling to the third dose cohort of the complementary Phase 1 study underway in China. Through these trials, which are evaluating different dosing administration regimens, we aim to inform the design of a future Phase 2 basket trial evaluating ON 123300 in multiple high unmet need indications, including CDK 4/6 inhibitor refractory HR+ HER2- metastatic breast cancer. Given ON 123300's ability in preclinical studies to overcome resistance to the most widely prescribed CDK 4/6 inhibitor, we believe this novel multi-kinase inhibitor has the potential to be a best-in-class therapy for this and other cancers."

Dr. Fruchtman continued, “Beyond our lead program, we also reported very encouraging preliminary results from the investigator-initiated study evaluating rigosertib plus nivolumab in advanced KRAS-mutated NSCLC. These results highlighted the doublet’s favorable safety profile and provided preliminary evidence of efficacy in an extremely challenging patient population. Additional preliminary data from the trial is expected to be presented at a RAS-focused medical meeting in September. Looking forward, we will continue to leverage investigator-initiated programs to further rigosertib’s clinical development, while maintaining our primary focus and resources on ON 123300. Milestones ahead for the remainder of the year include continued progress of our ON 123300 clinical trials, expansion of rigosertib investigator-initiated studies program, and potentially acquiring new assets to augment our pipeline. With a strong financial position and a talented management team that was recently bolstered by the appointment of Dr. Mark Gelder as CMO, we believe we are well positioned to take advantage of the product development opportunities presented.”

Second Quarter Financial Results

Cash and cash equivalents as of June 30, 2021 were $43.7 million, compared with $19.0 million as of December 31, 2020. The Company believes that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business operations for more than eighteen months.

Research and development expenses were $1.9 million for the second quarter of 2021, compared with $4.8 million for the second quarter of 2020. The decrease was primarily related to higher clinical trial and consulting expenses in the 2020 period due to the INSPIRE study.

General and administrative expenses were $2.9 million for the second quarter of 2021, compared with $2.6 million for the second quarter of 2020. The increase was primarily due to expenses related to special meetings by proxy in the 2021 period.

Net loss for the second quarter of 2021 was $4.2 million, or $0.27 per share on 15.8 million weighted average shares outstanding, compared with a net loss for the second quarter of 2020 of $7.4 million, or $0.65 per share on 11.3 million weighted average shares outstanding.

Conference Call and Webcast

Onconova will host an investment community conference call today beginning at 4:30 p.m. Eastern Time, during which management will discuss financial results for the second quarter of 2021, provide a business update and answer questions. Interested parties can participate by dialing (855) 428-5741 (domestic callers) or (210) 229-8823 (international callers) and using conference ID 3876025.

A live webcast of the conference call will be available in the Investors & Media section of the Company's website at www.onconova.com. A replay of the webcast will be available on the Onconova website for 90 days following the call.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. The Company has proprietary targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation.

Onconova's novel, proprietary multi-kinase inhibitor ON 123300 is being evaluated in two separate and complementary Phase 1 dose-escalation and expansion studies. These trials are currently underway in the United States and China.

Onconova's product candidate rigosertib is being studied in an investigator-initiated study program, including in a dose-escalation and expansion Phase 1/2a investigator-initiated study targeting patients with KRAS+ non-small cell lung cancer with oral rigosertib in combination with nivolumab.

For more information, please visit www.onconova.com.

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's expectations regarding the timing of Onconova's and investigator-initiated clinical development and data presentation plans, and the mechanisms and indications for Onconova's product candidates. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "preliminary," "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 the success and timing of Onconova's clinical trials, investigator-initiated trials and regulatory agency and institutional review board approvals of protocols, Onconova's collaborations, the timing of the Company's annual stockholder meeting, market conditions 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.

Company Contact:
Avi Oler
Onconova Therapeutics, Inc.
267-759-3680
ir@onconova.us
https://www.onconova.com/contact/

Investor Contact:
Bruce Mackle
LifeSci Advisors, LLC
646-889-1200
bmackle@lifesciadvisors.com

(Tables to follow)

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	June 30, 2021	December 31, 2020
Assets	*(unaudited)*	
Current assets:		
Cash and cash equivalents	$ 43,709	$ 19,025
Receivables	27	37
Prepaid expenses and other current assets	457	722
Total current assets	44,193	19,784
Property and equipment, net	45	52
Other non-current assets	140	150
Total assets	$ 44,378	$ 19,986
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,290	$ 4,833
Accrued expenses and other current liabilities	2,983	4,962
Deferred revenue	226	226
Total current liabilities	7,499	10,021
Warrant liability	530	321
Deferred revenue, non-current	3,356	3,469
Total liabilities	11,385	13,811
Stockholders' equity:		
Preferred stock	-	-
Common stock	158	124
Additional paid in capital	470,335	434,593
Accumulated other comprehensive income	2	14
Accumulated deficit	(437,502)	(428,556)
Total stockholders' equity	32,993	6,175
Total liabilities and stockholders' equity	$ 44,378	$ 19,986

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations *(unaudited)*

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six months months ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 57	$ 56	$ 113	$ 108
Operating expenses:				
General and administrative	2,850	2,594	5,067	4,401
Research and development	1,852	4,801	3,789	8,171
Total operating expenses	4,702	7,395	8,856	12,572
Loss from operations	(4,645)	(7,339)	(8,743)	(12,464)
Change in fair value of warrant liability	427	(56)	(209)	(119)
Other (loss) income, net	(13)	-	6	96
Net loss	(4,231)	(7,395)	(8,946)	(12,487)
Net loss per share of common stock, basic and diluted	$ (0.27)	$ (0.65)	$ (0.59)	$ (1.14)
Basic and diluted weighted average shares outstanding	15,780,863	11,303,508	15,201,719	10,996,624