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 11, 2022**

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:

☐ 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))

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 11, 2022, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2022, 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 11, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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 11, 2022

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Reports Second Quarter 2022 Financial Results and Provides Business Update

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

NEWTOWN, PA., August 11, 2022 (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, 2022, and provided a business update.

Highlights for the second quarter of 2022 and recent weeks include:

- Safety data from the ongoing Phase 1 solid tumor trials of narazaciclib in the United States and China continue to be encouraging with the maximum tolerated dose not yet reached in either study. The trial in the United States is currently enrolling its fifth dose escalation cohort, with continuous dosing. The trial in China is also enrolling its fifth dose escalation cohort but once a day on days 1-21 of 28-day cycles. A protocol amendment to enable further dose escalation in the trial in China is being prepared.

- Data from *in vitro* and cell-based assays that suggest narazaciclib's inhibitory profile may provide safety and efficacy advantages over currently approved CDK4/6 inhibitors were featured in an abstract published at the American Society of Clinical Oncology (ASCO) Annual Meeting.

- Each of rigosertib's investigator-sponsored trials continues to progress. A Phase 2 trial evaluating rigosertib plus pembrolizumab in patients with checkpoint inhibitor refractory metastatic melanoma is on schedule to be initiated in the second half of 2022. The expansion cohort of the Phase 1/2a trial of rigosertib plus nivolumab in patients with KRAS-mutated non-small cell lung cancer continues to enroll patients, with additional data from the trial expected in Q3 2022. The Phase 2 trial of rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa also continues to enroll patients.

- Mark Guerin was appointed Chief Operating Officer in addition to his role as Chief Financial Officer and Dr. Adar Makovski Silverstein was promoted to Senior Director and Head of Corporate Development.

- Cash and cash equivalents at June 30, 2022 were $46.5 million, which the Company believes will be sufficient to fund ongoing clinical trials and business operations for at least eighteen months.

Management Commentary

"We saw sustained progress across our pipeline over the past months and are well positioned to complete our current Phase 1 trials as we move through the second half of the year," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "Narazaciclib continues to show a favorable safety profile in its Phase 1 studies, which will be key to informing the design of future trials seeking to address the unmet needs posed by the limitations of currently available CDK4/6 inhibitors. These limitations stem from issues related to safety, tolerability, and primary and acquired drug resistance, which we believe narazaciclib's differentiated inhibitory profile may overcome. We were pleased to publish preclinical data supporting this hypothesis at the most recent ASCO meeting and look forward to continued efforts to translate these promising findings to the clinic."

Dr. Fruchtman continued, "Alongside narazaciclib's advancement, we also made key progress in rigosertib's investigator-sponsored studies. This includes a Phase 2 trial evaluating rigosertib combined with a PD-1 checkpoint inhibitor in checkpoint inhibitor refractory metastatic melanoma which is on schedule to open for enrollment in the second half of 2022. This study seeks to leverage rigosertib's immunomodulatory effects and is supported by initial data from the ongoing trial of rigosertib plus anti-PD-1 therapy in KRAS-mutated NSCLC. These data provided strong evidence of the studied doublet's activity in patients who previously failed checkpoint inhibitor therapy, which is a finding we aim to build upon with the presentation of additional data at a medical meeting later this quarter. Data has been presented, which will be updated, demonstrating that responses seen with rigosertib in this setting are agnostic to the type of KRAS mutation present. This upcoming milestone highlights how rigosertib's investigator-sponsored studies enable the capital efficient pursuit of value creating opportunities to complement our lead narazaciclib program."

Second Quarter Financial Results

Cash and cash equivalents as of June 30, 2022, were $46.5 million, compared with $55.1 million as of December 31, 2021. The Company believes that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business operations for at least eighteen months.

Research and development expenses were $2.0 million for the second quarter of 2022, compared with $1.9 million for the second quarter of 2021.

General and administrative expenses were $2.1 million for the second quarter of 2022, compared with $2.9 million for the second quarter of 2021.

Net loss for the second quarter of 2022 was $4.0 million, or $0.19 per share on 20.9 million weighted shares outstanding, compared with a net loss of $4.2 million, or $0.27 per share for the second quarter of 2021 on 15.8 million weighted 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 2022, provide a business update, and answer questions. Interested parties can participate by dialing (800) 289-0571 (domestic callers) or (856) 344-9290 (international callers) and using conference ID 3600715.

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 narazaciclib (formerly 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-sponsored study program, including in a dose-escalation and expansion Phase 1/2a investigator-sponsored study with oral rigosertib in combination with nivolumab for patients with KRAS+ non-small cell lung cancer.

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,” “encouraging,” "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, 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.

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(Tables to follow)

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

	June 30 2022	December 31, 2021
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 46,533	$ 55,070
Receivables	28	28
Prepaid expenses and other current assets	1,472	332
Total current assets	48,033	55,430
Property and equipment, net	31	38
Other non-current assets	10	10
Total assets	$ 48,074	$ 55,478
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,003	$ 2,757
Accrued expenses and other current liabilities	3,231	3,132
Deferred revenue	226	226
Total current liabilities	6,460	6,115
Deferred revenue, non-current	3,130	3,243
Total liabilities	9,590	9,358
Stockholders' equity:		
Preferred stock	-	-
Common stock	209	209
Additional paid in capital	491,181	490,644
Accumulated other comprehensive loss	(41)	(14)
Accumulated deficit	(452,865)	(444,719)
Total stockholders' equity	38,484	46,120
Total liabilities and stockholders' equity	$ 48,074	$ 55,478

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,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 57	$ 57	$ 113	$ 113
Operating expenses:				
General and administrative	2,139	2,850	4,325	5,067
Research and development	2,038	1,852	4,040	3,789
Total operating expenses	4,177	4,702	8,365	8,856
Loss from operations	(4,120)	(4,645)	(8,252)	(8,743)
Change in fair value of warrant liability	-	427	-	(209)
Other income (loss,) net	96	(13)	106	6
Net loss	(4,024)	(4,231)	(8,146)	(8,946)
Net loss per share of common stock, basic and diluted	$ (0.19)	$ (0.27)	$ (0.39)	$ (0.59)
Basic and diluted weighted average shares outstanding	20,904,085	15,780,863	20,904,085	15,201,719