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 15, 2023**

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 ☐

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2023, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023, 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 May 15, 2023
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: May 15, 2023

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Reports First Quarter 2023 Financial Results and Provides Business Update

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

NEWTOWN, PA. May 15, 2023 (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 March 31, 2023, and provided a business update.

Highlights for the first quarter of 2023 and recent weeks include:

- The first participant was dosed in the Phase 1/2a trial of narazaciclib combined with letrozole in recurrent metastatic low-grade endometrioid endometrial cancer (LGEEC). The trial remains on track for a preliminary data readout from its Phase 1 portion in the fourth quarter of this year.

- Safety data from the Phase 1 solid tumor trial evaluating a continuous daily dosing schedule of narazaciclib continue to be encouraging with the maximum tolerated dose awaiting confirmation. The trial has enrolled patients in its sixth dose escalation cohort, which evaluates a 240 mg oral dose of narazaciclib.

- Two posters presented at the American Association for Cancer Research (AACR) Annual Meeting featured the results of preclinical studies of narazaciclib. Data showed that, in addition to inhibiting kinases such as CDK 4 and CDK 6, narazaciclib treatment led to the degradation of other kinases not targeted by the FDA-approved CDK 4/6 inhibitor palbociclib. These kinases included BUB1, the overexpression of which was shown to be associated with poor prognosis in breast cancer and uterine corpus endometrial carcinomas. In addition, data presented showed that narazaciclib's activity in several preclinical cancer models compared favorably to that of FDA-approved CDK 4/6 inhibitors.

- The second of two evaluable participants in the investigator-sponsored Phase 2 program evaluating rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC) achieved a complete clinical response of all cancerous skin lesions following four treatment cycles of oral rigosertib. Thus, both patients evaluable for response achieved complete cutaneous remissions (CCR). This data and the rational for the study of rigosertib in RDEB-SCC was presented at the recent meeting of the Society of Investigative Dermatology Meeting in Osaka, Japan. Onconova has requested a Type B Meeting to review these initial data with the U.S. Food and Drug Administration (FDA), with the goal of identifying the optimal regulatory path for rigosertib in RDEB-associated SCC. Onconova expects to provide an update on the Type B meeting after it has received written feedback from the agency.

- Rigosertib's additional investigator-sponsored trials continue to progress. A Phase 2 trial of rigosertib combined with Merck's anti-PD-1 therapy KEYTRYDA® (pembrolizumab) in checkpoint inhibitor refractory melanoma recently opened for enrollment. The Phase 1/2a trial of rigosertib in combination with Bristol Meyer Squibb's OPDIVO® (nivolumab) in KRAS-mutated non-small cell lung cancer (NSCLC) is ongoing. Based on previously reported data that showed an encouraging signal of efficacy and that the studied doublet was well tolerated. The NSCLC trial protocol has been amended to add cohorts evaluating increasing doses of rigosertib in combination with the standard dose of nivolumab. Data from these additional cohorts are expected alongside updated data from the trial's earlier cohorts in 2023.

- Onconova recently entered into a collaboration agreement with Pangea Biomed. The collaboration will leverage Pangea Biomed's proprietary algorithmic platform, ENLIGHT, with the goal of identifying biomarkers of response to rigosertib. Onconova retains all rights to rigosertib and will own intellectual property that may result from the research collaboration.

- Preclinical data characterizing rigosertib's multi-faceted mechanism of action were recently featured in a poster presentation at the AACR Targeting RAS Conference.

Management Commentary

"Recent progress has us approaching important clinical and regulatory milestones expected later this year," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "We recently dosed the first participant in our Phase 1/2a trial of narazaciclib plus letrozole in recurrent metastatic LGEEC. This trial is supported by prior clinical data providing proof-of-concept for the studied doublet's mechanism of action, as well as preclinical and Phase 1 results that suggest narazaciclib can overcome the shortcomings of the off-label agents current combined with letrozole to treat this indication. Collectively, these data fuel our enthusiasm for the program as we advance towards a preliminary data readout expected in the fourth quarter."

Dr. Fruchtman continued, "In rigosertib's RDEB-associated SCC program, we have requested a Type B meeting to discuss our encouraging clinical data with the FDA and expect to provide an important regulatory update following the meeting. Though from a small number of patients, these data have far exceeded our expectations, with both of the program's participants achieving durable, complete clinical responses of all cancerous skin lesions on rigosertib monotherapy. Given the strength of these data, the ultra-rare nature of RDEB-associated SCC, and the stark limitations of currently available therapies, we are committed to working with the agency to determine the best, most expeditious path towards a potential approval."

First Quarter Financial Results

Cash and cash equivalents as of March 31, 2023 were $34.2 million compared with $38.8 million as of December 31, 2022. The company believes that its cash and cash equivalents will be sufficient to fund ongoing clinical trials and business operations into the first quarter of 2024.

Research and development expenses were $4.1 million for the first quarter of 2023, compared with $2.0 million for the first quarter of 2022.

General and administrative expenses were $2.1 million for the first quarter of 2023, compared with $2.2 million for the first quarter of 2022.

Net loss for the first quarter of 2023 was $5.8 million, or $0.28 per share on 20.9 million weighted shares outstanding, compared with a net loss of $4.1 million, or $0.20 per share for the first quarter of 2022 on 20.9 million weighted shares outstanding.

Conference Call and Webcast

Onconova will host an investment community conference call beginning at 4:30 p.m. Eastern Time, during which management will discuss financial results for the first quarter of 2023, provide a business update, and answer questions. Interested parties can participate by dialing (800) 715-9871 (domestic callers) or (646) 307-1963 (international callers) and using conference ID 9090989.

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 a combination trial with estrogen blockade in advanced endometrial cancer. Based on preclinical and clinical studies of CDK 4/6 inhibitors, Onconova is also evaluating opportunities for combination studies with narazaciclib in additional indications.

Onconova's product candidate rigosertib is being studied in multiple investigator-sponsored studies, including a dose-escalation and expansion Phase 1/2a study of oral rigosertib in combination with nivolumab in patients with KRAS+ non-small cell lung cancer, a Phase 2 program evaluating rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC), and in advanced malignant melanoma.

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 its clinical development and trials, its product candidates, its business and financial position. 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.

Company Contact:
Mark Guerin
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

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 34,220	$ 38,757
Receivables	17	29
Prepaid expenses and other current assets	802	561
Total current assets	35,039	39,347
Property and equipment, net	21	24
Other non-current assets	1	1
Total assets	$ 35,061	$ 39,372
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,896	$ 3,860
Accrued expenses and other current liabilities	4,102	3,960
Deferred revenue	226	226
Total current liabilities	9,224	8,046
Deferred revenue, non-current	2,961	3,017
Total liabilities	12,185	11,063
Stockholders' equity:		
Preferred stock	-	-
Common stock	210	209
Additional paid in capital	492,151	491,816
Accumulated other comprehensive loss	(27)	(33)
Accumulated deficit	(469,458)	(463,683)
Total stockholders' equity	22,876	28,309
Total liabilities and stockholders' equity	$ 35,061	$ 39,372

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2023	**2022**
Revenue	$ 56	$ 56
Operating expenses:		
General and administrative	2,113	2,186
Research and development	4,080	2,002
Total operating expenses	6,193	4,188
Loss from operations	(6,137)	(4,132)
Other income, net	362	10
Net loss	(5,775)	(4,122)
Net loss per share of common stock, basic and diluted	$ (0.28)	$ (0.20)
Basic and diluted weighted average shares outstanding	20,960,171	20,904,085