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): **March 16, 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 March 16, 2023, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 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 March 16, 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: March 16, 2023

Onconova Therapeutics, Inc.

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

Exhibit 99.1

Onconova Therapeutics Reports Full Year 2022 Financial Results and Provides Business Update

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

NEWTOWN, PA., March 16, 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 twelve months ended December 31, 2022, and provided a business update.

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

- Based upon encouraging safety findings from its ongoing Phase 1 program, Onconova intends to administer narazaciclib orally with a continuous daily dosing schedule in upcoming clinical trials. Results from the Phase 1 solid tumor trial evaluating a continuous daily dosing regimen of narazaciclib showed that the maximum tolerated dose was not reached through the fifth dose escalation cohort. The Phase 1 trial will advance to its sixth dose escalation cohort, which will evaluate a dose of 240 mg orally on a continuous daily schedule.

- The Phase 1/2a trial of narazaciclib combined with letrozole in recurrent metastatic low-grade endometrioid endometrial cancer (LGEEC) is expected to open for enrollment in the first quarter of 2023. The trial remains on track for a preliminary data readout from its Phase 1 portion in the fourth quarter of 2023.

- Two abstracts describing the results of preclinical studies of narazaciclib were recently accepted for poster presentations at the upcoming American Association for Cancer Research (AACR) Annual Meeting. The abstracts, which are available on the AACR website, are titled "Differential targets engaged by narazaciclib in comparison to the approved CDK4/6 inhibitors contribute to enhanced inhibition of tumor cell growth" and "Synergistic activity of the CDK4/6 antagonist narazaciclib (ON123300) with irreversible BTK inhibition in ibrutinib-resistant mantle cell lymphoma."

- The investigator-sponsored Phase 2 program evaluating rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC) continues to progress and remains open for enrollment. The second of two evaluable participants in the program recently achieved a complete clinical response of all cancerous skin lesions following four treatment cycles of oral rigosertib. The program's first evaluable participant previously achieved a complete response. Both participants remain on therapy and have maintained their response to therapy to-date. Onconova intends to review the program's initial data with regulators to gain insight on the optimal regulatory path for rigosertib in RDEB-associated SCC, an ultra-rare and invariably fatal condition.

- Rigosertib's additional investigator-sponsored trials also continue to progress. The Phase 1/2a trial evaluating rigosertib in combination with nivolumab in KRAS-mutated (KRAS+) non-small cell lung cancer (NSCLC) continues to enroll patients in its dose-expansion cohort, with additional data from the trial expected in the second quarter of 2023. A Phase 2 trial of rigosertib in combination with pembrolizumab in patients with checkpoint inhibitor refractory metastatic melanoma is expected to open for enrollment later this quarter.

- Data from cell-based and *in vitro* assays characterizing rigosertib's multi-faceted mechanism of action were recently featured in a poster presentation at the AACR Targeting RAS Conference.

Management Commentary

"We recently received IRB approval at New York University Langone Health for our Phase 1/2a trial of narazaciclib plus letrozole in recurrent LGEEC, which is on track for an important preliminary readout later this year," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova. "Prior preclinical data as well as single arm and randomized Phase 2 clinical data provide strong proof-of-concept for narazaciclib's mechanism of action in LGEEC and demonstrate its potential to overcome the numerous shortcomings of the CDK 4/6 inhibitors that are currently used off-label in combination with letrozole in this indication. We look forward to building on these datasets in our upcoming trial, which we believe will further highlight the advantages of narazaciclib's differentiated kinase inhibitory profile."

Dr. Fruchtman continued, "Recent progress in rigosertib's investigator-sponsored trials was highlighted by data from our RDEB-associated SCC program. With both of the program's evaluable participants achieving a complete clinical response of all cancerous skin lesions with rigosertib monotherapy, we now intend to engage with regulators to identify the most expeditious path to a potential approval in this ultra-orphan indication. In addition, trials of rigosertib combined with checkpoint inhibition continue to advance, with a Phase 2 study in checkpoint-inhibitor refractory melanoma expected to open for enrollment later this quarter and additional data from a Phase 1/2a trial in KRAS-mutated NSCLC expected next quarter. Looking forward, we expect the continued progress of these investigator-sponsored trials to provide an important source of value to complement our lead narazaciclib program, which remains our primary focus."

Full Year Financial Results

Cash and cash equivalents as of December 31, 2022, were $38.8 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 into the first quarter of 2024.

Research and development expenses were $11.4 million for 2022, compared with $7.3 million for 2021. The increase was primarily related to the narazaciclib development program and drug manufacturing.

General and administrative expenses were $8.4 million for 2022, compared with $9.4 million for 2021. The decrease was primarily related to lower costs for our annual general meeting than in the 2021 period.

Net loss for 2022 was $19.0 million, or $0.91 per share on 20.9 million weighted average shares outstanding, compared with a net loss of $16.2 million, or $0.96 per share for 2021 based on 16.8 million weighted average 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 full year 2022, 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 3097517.

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. Based on preclinical and clinical studies of CDK 4/6 inhibitors, Onconova is also planning a combination trial of narazaciclib with estrogen blockade in advanced endometrial cancer, as well as its clinical study 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, and a Phase 2 program evaluating rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC).

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.

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ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(in thousands)

	December 31, 2022	December 31, 2021
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 38,757	$ 55,070
Receivables	29	28
Prepaid expenses and other current assets	561	332
Total current assets	39,347	55,430
Property and equipment, net	24	38
Other non-current assets	1	10
Total assets	$ 39,372	$ 55,478
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,860	$ 2,757
Accrued expenses and other current liabilities	3,960	3,132
Deferred revenue	226	226
Total current liabilities	8,046	6,115
Deferred revenue, non-current	3,017	3,243
Total liabilities	11,063	9,358
Stockholders' equity:		
Preferred stock	-	-
Common stock	209	209
Additional paid in capital	491,816	490,644
Accumulated other comprehensive loss	(33)	(14)
Accumulated deficit	(463,683)	(444,719)
Total stockholders' equity	28,309	46,120
Total liabilities and stockholders' equity	$ 39,372	$ 55,478

ONCONOVA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	**2021**
	(unaudited)	
Revenue	$ 226	$ 226
Operating expenses:		
General and administrative	8,447	9,425
Research and development	11,406	7,297
Total operating expenses	19,853	16,722
Loss from operations	(19,627)	(16,496)
Change in fair value of warrant liability	-	321
Other income, net	663	12
Net loss	(18,964)	(16,163)
Net loss per share of common stock, basic and diluted	$ (0.91)	$ (0.96)
Basic and diluted weighted average shares outstanding	20,908,235	16,832,198