# 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): **November 14, 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 November 14, 2023, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and nine months ended September 30, 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 November 14, 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: November 14, 2023

Onconova Therapeutics, Inc.

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

**Exhibit 99.1**

**Onconova Therapeutics Reports Corporate Update and Announces Third Quarter 2023 Financial Results**

*Narazaciclib progressing towards registrational studies; target engagement and acceptable safety profile support further dose escalation, affirming differentiated profile*

*Update on the registrational preparations for the narazaciclib program and the rigosertib trial plan expected in the first half of 2024*

*Company to host conference call and webcast at 4:30 p.m. ET on Tuesday, November 14, 2023*

**NEWTOWN, Pa., November 14, 2023** (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), ("Onconova" or "the Company"), a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, today reported third quarter 2023 financial results and provided an update on recent pipeline progress. Management plans to host a conference call and live webcast at 4:30 p.m. ET today to discuss these results.

"Onconova has made excellent progress in the third quarter of 2023. Starting with our lead program, **narazaciclib**, a differentiated inhibitor of multiple kinases including CDK4/6, we advanced the registrational trial preparations in the first indication, for patients with low grade endometrioid endometrial cancer (LGEEC). CDK4/6 inhibitors have substantially changed the face of cancer care for the better and become a multibillion-dollar drug class. We believe **narazaciclib** has the potential to be differentiated by potently targeting proteins putatively involved in the resistance pathways of cancer cells that the approved agents fail to significantly inhibit," said Steve Fruchtman, M.D., President and Chief Executive Officer.

Dr. Fruchtman continued, "We are seeing **clinical and biological target engagement with narazaciclib and an acceptable safety profile at therapeutic dosing levels** in the Phase 1/2 program. To date, we have not seen significant neutropenia and thus remain on target to deliver narazaciclib as a daily anti-cancer drug not requiring time off to permit marrow recovery, in contrast to the most commonly prescribed CDK4/6 inhibitor. In addition, to date, narazaciclib has not caused significant diarrhea, another limitation of other CDK4/6 inhibitors. Based on this profile, we have decided to dose escalate to at least one more cohort in each of the ongoing U.S. studies, to ensure that we achieve the optimal recommended Phase 2 dose. This may extend the Phase 1/2 program into the first quarter of 2024. We believe this is very good news for the program because it underscores the potential for narazaciclib to have a differentiated safety profile and wide therapeutic index."

"From a corporate perspective, in the third quarter, we named **Dr. Victor Moyo as Chief Medical Officer** and **Meena Arora as Vice-President, Global Medical Affairs & Research and Development**, putting us on very solid footing to advance the clinical plan and regulatory strategy for narazaciclib and rigosertib. In addition, we continue to actively engage in a range of discussions related to partnering opportunities, to support the progression of our programs," continued Dr. Fruchtman. "Finally, we progressed the development of a registrational study plan for **rigosertib**, our cell pathway inhibitor, for the ultra-rare indication of recessive dystrophic epidermolysis bullosa-associated squamous cell carcinoma (RDEB-associated SCC). These developments were complemented by **impressive medical meeting presentations** on both programs by our collaborators."

**Near Term Narazaciclib Milestones:** Onconova intends to:

- present preclinical data at two December medical meetings: the San Antonio Breast Cancer Symposium (SABCS) and the annual meeting of the American Society of Hematology (ASH);
- continue the dose escalation segment of the Phase 1/2 program which may bring us into the first quarter of 2024;
- provide a read-out on narazaciclib's safety and pharmacology in the first half of 2024;
- provide an update on our registrational trial-readiness over the next few quarters, including the definition of our recommended Phase 2 dose, engagement with the FDA on the pivotal trial design, and continuing to work with external clinical experts including the Gynecologic Oncology Group (GOG), and the European Network for Gynecologic Oncology Trials (ENGOT).

Achievement of these milestones will also enable us to establish a solid foundation to expand the program to include other indications such as breast cancer, ovarian cancer, and mantle cell lymphoma.

**Rigosertib milestones:** Onconova confirms plans to provide an update on the next steps to obtain orphan designation for rigosertib in RDEB-associated SCC and for the registrational program in the first half of 2024.

**Second Quarter Financial Results**

Cash and cash equivalents as of September 30, 2023, were $25.2 million, compared to $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 into the third quarter of 2024.

Research and development expenses were $2.5 million for the third quarter of 2023, compared with $3.6 million for the second quarter of 2022.

General and administrative expenses were $2.7 million for the third quarter of 2023, compared with $2.1 million for the second quarter of 2022.

Net loss for the third quarter of 2023 was $4.7 million, or $0.23 per share on 21.0 million weighted average shares outstanding, compared with a net loss of $5.4 million, or $0.26 per share for the third quarter of 2022 on 20.9 million weighted average shares outstanding.

***Conference Call and Webcast Information***

Interested parties who wish to participate in the conference call may do so by dialing:

- (800) 715-9871 for domestic and
- (646) 307-1963 for international callers and
- Using conference ID 3238751

Those interested in listening to the conference call via the internet may do so by visiting the investors and media page on the Company's website at www.onconova.com and clicking on the webcast link. In addition to the live webcast, a replay 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's product candidates, narazaciclib and rigosertib, are proprietary targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation.

Narazaciclib, Onconova's novel, multi-kinase inhibitor (formerly ON 123300), is being evaluated in a Phase 1/2 combination trial with the estrogen blocker letrozole, in advanced endometrial cancer (NCT05705505). Based on preclinical and clinical studies of CDK 4/6 inhibitors, Onconova believes narazaciclib has broad potential and is also evaluating opportunities for combination studies with narazaciclib and letrozole in additional indications, including breast cancer, ovarian cancer and mantle cell lymphoma.

Rigosertib is being studied in an investigator-sponsored trial strategy to evaluate the product candidate in multiple indications, 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 (NCT04263090), a Phase 2 program evaluating oral or IV rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB-associated SCC) (NCT03786237, NCT04177498), and a Phase 2 trial evaluating rigosertib in combination with pembrolizumab in patients with metastatic melanoma (NCT05764395).

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)*

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| | *(unaudited)* | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 25,244 | $ 38,757 |
| Receivables | 18 | 29 |
| Prepaid expenses and other current assets | 1,749 | 561 |
| Total current assets | 27,011 | 39,347 |
| Property and equipment, net | 26 | 24 |
| Other non-current assets | 1 | 1 |
| Total assets | $ 27,038 | $ 39,372 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 6,148 | $ 3,860 |
| Accrued expenses and other current liabilities | 3,300 | 3,960 |
| Deferred revenue | 226 | 226 |
| Total current liabilities | 9,674 | 8,046 |
| Deferred revenue, non-current | 2,847 | 3,017 |
| Total liabilities | 12,521 | 11,063 |
| | | |
| Stockholders' equity: | | |
| Preferred stock | - | - |
| Common stock | 210 | 209 |
| Additional paid in capital | 492,784 | 491,816 |
| Accumulated other comprehensive loss | (30) | (33) |
| Accumulated deficit | (478,447) | (463,683) |
| Total stockholders' equity | 14,517 | 28,309 |
| Total liabilities and stockholders' equity | $ 27,038 | $ 39,372 |

**ONCONOVA THERAPEUTICS, INC.**

**Condensed Consolidated Statements of Operations (unaudited)**

*(in thousands, except share and per share amounts)*

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Revenue | $ 57 | $ 57 | $ 170 | $ 170 |
| Operating expenses: | | | | |
| General and administrative | 2,686 | 2,105 | 7,010 | 6,430 |
| Research and development | 2,460 | 3,593 | 8,996 | 7,633 |
| Total operating expenses | 5,146 | 5,698 | 16,006 | 14,063 |
| Loss from operations | (5,089) | (5,641) | (15,836) | (13,893) |
| | | | | |
| Other income, net | 350 | 243 | 1,072 | 349 |
| Net loss | (4,739) | (5,398) | (14,764) | (13,544) |
| Net loss per share of common stock, basic and diluted | $ (0.23) | $ (0.26) | $ (0.70) | $ (0.65) |
| Basic and diluted weighted average shares outstanding | 21,002,937 | 20,915,408 | 20,981,097 | 20,920,251 |