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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2023

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-36020

Onconova Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**22-3627252**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
12 Penns Trail, Newtown, PA	**18940**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(267) 759-3680**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). ☐ Yes ☒ No

The number of outstanding shares of the registrant's Common Stock, par value $0.01 per share, as of August 1, 2023 was 20,977,625.

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

ONCONOVA THERAPEUTICS, INC.

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FOR THE QUARTER ENDED JUNE 30, 2023

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Onconova Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2023	December 31, 2022
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 29,729,000	$ 38,757,000
Receivables	17,000	29,000
Prepaid expenses and other current assets	704,000	561,000
Total current assets	30,450,000	39,347,000
Property and equipment, net	17,000	24,000
Other non-current assets	1,000	1,000
Total assets	$ 30,468,000	$ 39,372,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,071,000	$ 3,860,000
Accrued expenses and other current liabilities	3,369,000	3,960,000
Deferred revenue	226,000	226,000
Total current liabilities	8,666,000	8,046,000
Deferred revenue, non-current	2,904,000	3,017,000
Total liabilities	11,570,000	11,063,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 shares authorized, none issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value, 125,000,000 shares authorized, 20,977,625 and 20,925,992 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	210,000	209,000
Additional paid in capital	492,424,000	491,816,000
Accumulated deficit	(473,708,000)	(463,683,000)
Accumulated other comprehensive loss	(28,000)	(33,000)
Total stockholders' equity	18,898,000	28,309,000
Total liabilities and stockholders' equity	$ 30,468,000	$ 39,372,000

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Condensed Consolidated Statements of Operations (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue	$ 57,000	$ 57,000	$ 113,000	$ 113,000
Operating expenses:				
General and administrative	2,211,000	2,139,000	4,324,000	4,325,000
Research and development	2,456,000	2,038,000	6,536,000	4,040,000
Total operating expenses	4,667,000	4,177,000	10,860,000	8,365,000
Loss from operations	(4,610,000)	(4,120,000)	(10,747,000)	(8,252,000)
Other income, net	360,000	96,000	722,000	106,000
Net loss	$ (4,250,000)	$ (4,024,000)	$ (10,025,000)	$ (8,146,000)
Net loss per share, basic and diluted	$ (0.20)	$ (0.19)	$ (0.48)	$ (0.39)
Basic and diluted weighted average shares outstanding	20,979,766	20,904,085	20,970,022	20,904,085

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (4,250,000)	$ (4,024,000)	$ (10,025,000)	$ (8,146,000)
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustments, net	(1,000)	(20,000)	5,000	(27,000)
Other comprehensive income (loss), net of tax	(1,000)	(20,000)	5,000	(27,000)
Comprehensive loss	$ (4,251,000)	$ (4,044,000)	$ (10,020,000)	$ (8,173,000)

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Consolidated Statement of Stockholders' Equity (Deficit) (unaudited)

	Three Month Periods Ended June 30, 2023 and 2022					
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total
	Shares	Amount				
Balance at March 31, 2023	20,969,559	$ 210,000	$ 492,151,000	$ (469,458,000)	$ (27,000)	$ 22,876,000
Net loss	—	—	—	(4,250,000)	—	(4,250,000)
Other comprehensive loss	—	—	—	—	(1,000)	(1,000)
Stock-based compensation	—	—	273,000	—	—	273,000
Shares issued for vested restricted stock units	8,066	—	—	—	—	—
Balance at June 30, 2023	20,977,625	$ 210,000	$ 492,424,000	$ (473,708,000)	$ (28,000)	$ 18,898,000
Balance at March 31, 2022	20,895,563	$ 209,000	$ 490,940,000	$ (448,841,000)	$ (21,000)	$ 42,287,000
Net loss	—	—	—	(4,024,000)	—	(4,024,000)
Other comprehensive loss	—	—	—	—	(20,000)	(20,000)
Stock-based compensation	—	—	241,000	—	—	241,000
Balance at June 30, 2022	20,895,563	$ 209,000	$ 491,181,000	$ (452,865,000)	$ (41,000)	$ 38,484,000

	Six Month Periods Ended June 30, 2023 and 2022					
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount				
Balance at December 31, 2022	20,925,992	$ 209,000	$ 491,816,000	$ (463,683,000)	$ (33,000)	$ 28,309,000
Net loss	—	—	—	(10,025,000)	—	(10,025,000)
Other comprehensive loss	—	—	—	—	5,000	5,000
Stock-based compensation	—	—	609,000	—	—	609,000
Shares issued for vested restricted stock units	51,633	1,000	(1,000)	—	—	—
Balance at June 30, 2023	20,977,625	$ 210,000	$ 492,424,000	$ (473,708,000)	$ (28,000)	$ 18,898,000
Balance at December 31, 2021	20,895,563	$ 209,000	$ 490,644,000	$ (444,719,000)	$ (14,000)	$ 46,120,000
Net loss	—	—	—	(8,146,000)	—	(8,146,000)
Other comprehensive loss	—	—	—	—	(27,000)	(27,000)
Stock-based compensation	—	—	537,000	—	—	537,000
Balance at June 30, 2022	20,895,563	$ 209,000	$ 491,181,000	$ (452,865,000)	$ (41,000)	$ 38,484,000

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows (unaudited)

	Six Months Ended June 30,	
	2023	2022
Operating activities:		
Net loss	$ (10,025,000)	$ (8,146,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,000	7,000
Stock compensation expense	609,000	537,000
Changes in assets and liabilities:		
Receivables	12,000	—
Prepaid expenses and other current assets	(143,000)	(1,140,000)
Accounts payable	1,211,000	246,000
Accrued expenses and other current liabilities	(591,000)	99,000
Deferred revenue	(113,000)	(113,000)
Net cash used in operating activities	(9,033,000)	(8,510,000)
Effect of foreign currency translation on cash	5,000	(27,000)
Net decrease in cash and cash equivalents	(9,028,000)	(8,537,000)
Cash and cash equivalents at beginning of period	38,757,000	55,070,000
Cash and cash equivalents at end of period	$ 29,729,000	$ 46,533,000

See accompanying notes to condensed consolidated financial statements.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Nature of Business

The Company

Onconova Therapeutics, Inc. (the Company) was incorporated in the State of Delaware on December 22, 1998 and commenced operations on January 1, 1999. The Company's headquarters are located in Newtown, Pennsylvania. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. The Company has proprietary molecularly targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation. The Company believes that the product candidates in its pipeline have the potential to be efficacious in a variety of cancers with unmet medical need. The Company has the following two clinical-stage programs: 1. narazaciclib (ON 123300), a multi-kinase inhibitor in solid tumors and hematological malignancies as a single agent or in combination with other anti-cancer therapies; and 2. oral rigosertib administered alone or in combination for the treatment of various cancers. The Company is currently evaluating potential compounds for in-licensing opportunities. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe.

Liquidity

The Company has incurred recurring operating losses since inception. For the six months ended June 30, 2023, the Company incurred a net loss of $10,025,000 and as of June 30, 2023 the Company had generated an accumulated deficit of $473,708,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At June 30, 2023, the Company had cash and cash equivalents of $29,729,000. The Company believes that its cash and cash equivalents will be sufficient to fund its ongoing trials and business operations into the second quarter of 2024; therefore, based on current projections, the Company does not have sufficient cash and cash equivalents to support its operations for at least the 12 months following the date that these financial statements are issued. These conditions raise substantial doubt about the Company’s ability to continue as a going concern through the one year period after the date that the financial statements are issued. Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, the Company may have based this estimate on assumptions that may prove to be wrong, and the Company's operating plan may change as a result of many factors currently unknown to the Company.

The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy. To alleviate the conditions that raise substantial doubt about the Company’s ability to continue as a going concern, management plans to explore various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on the Company’s business, results of operations, and financial condition. Accordingly, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Certain information and footnotes normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). The financial statements include the consolidated accounts of the Company and its wholly-owned subsidiary, Onconova Europe GmbH. All significant intercompany transactions have been eliminated.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of June 30, 2023, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2023 and 2022, the consolidated statements of stockholders' equity (deficit) for the three and six months ended June 30, 2023 and 2022 and the condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2023, the results of its operations for the three and six months ended June 30, 2023 and 2022, and its cash flows for the six months ended June 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2023 and 2022 are unaudited. The results for the three and six months ended June 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2022 included in the Company's annual report on Form 10-K filed with the SEC on March 30, 2023.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which is the identification and development of oncology therapeutics.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains a portion of its cash and cash equivalent balances in the form of money market accounts with financial institutions that management believes are creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

At June 30, 2023 the Company had $29,729,000 of its cash and cash equivalents in a Morgan Stanley Institutional Liquidity Fund. The fund is a AAA rated money market fund that invests in a portfolio of liquid, high-quality debt securities issued by the U.S. government. The fund resides in a custodial account held by U.S. Bank for which SVB Asset Management is the advisor.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2022 included in the Company's annual report on Form 10-K filed with the SEC on March 30, 2023. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

Fair Value Measurements

At both June 30, 2023 and December 31, 2002, the Company had no financial assets and liabilities measured at fair value on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

Recent Accounting Pronouncements

In June 2016, the FASB issued new guidance on the accounting for credit losses on financial instruments. The guidance was amended in November 2019. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The guidance was effective for fiscal years beginning after December 15, 2022, and interim periods within those years, for companies deemed to be smaller reporting companies as of November 15, 2019, with early adoption permitted. The Company adopted the guidance effective January 1, 2023. The guidance did not have a material effect on the Company's consolidated financial statements.

3. Revenue

The Company's revenue during the three and six months ended June 30, 2023 and 2022 was from its license and collaboration agreement with SymBio.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Symbio				
Upfront license fee recognition over time	$ 57,000	$ 57,000	$ 113,000	$ 113,000

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

Deferred revenue is as follows:

	Symbio Upfront Payment
Deferred balance at December 31, 2022	$ 3,243,000
Recognition to revenue	(113,000)
Deferred balance at June 30, 2023	$ 3,130,000

4. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at June 30, 2023 and 2022 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive (reflects the number of common shares as if the dilutive securities had been converted to common stock):

	June 30,	
	2023	2022
Warrants	344,990	491,586
Stock options	1,711,797	850,553
	2,056,787	1,342,139

5. Warrants

Common Stock warrants are accounted for in accordance with applicable accounting guidance provided in ASC Topic 815, *Derivatives and Hedging - Contracts in Entity's Own Equity* (ASC Topic 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

Warrants outstanding and warrant activity (reflects the number of common shares as if the warrants were converted to common stock) for the six months ended June 30, 2023 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2022	Warrants Issued	Warrants Exercised	Warrants Expired	Balance June 30, 2023
Non-tradable pre-funded warrants	Equity	$ 2.25	July 2023	26	—	—	—	26
Non-tradable pre-funded warrants	Equity	$ 2.25	none	3,522	—	—	—	3,522
Non-tradable pre-funded warrants	Equity	$ 2.25	none	4,974	—	—	—	4,974
Non-tradable warrants	Equity	$ 30.00	September 2023	7,306	—	—	—	7,306
Non-tradable warrants	Equity	$ 3.00	November 2024	244,500	—	—	—	244,500
Non-tradable warrants	Equity	$ 6.54375	December 2024	16,953	—	—	—	16,953
Non-tradable warrants	Equity	$ 6.75450	December 2024	46,263	—	—	—	46,263
Non-tradable warrants	Equity	$ 6.77850	December 2023	29,968	—	—	—	29,968
				353,512	—	—	—	353,512

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

6. Balance Sheet Detail

Prepaid expenses and other current assets:

	June 30, 2023	December 31, 2022
Research and development	$ 280,000	$ 233,000
Manufacturing	98,000	97,000
Insurance	62,000	191,000
Other	264,000	40,000
	$ 704,000	$ 561,000

Property and equipment:

	June 30, 2023	December 31, 2022
Property and equipment	$ 70,000	$ 70,000
Accumulated depreciation	(53,000)	(46,000)
	$ 17,000	$ 24,000

Accrued expenses and other current liabilities:

	June 30, 2023	December 31, 2022
Research and development	$ 2,467,000	$ 2,593,000
Employee compensation	742,000	1,187,000
Professional fees	160,000	180,000
	$ 3,369,000	$ 3,960,000

7. Stock-Based Compensation

The 2018 Omnibus Incentive Compensation Plan (the “2018 Plan”) was unanimously approved by the Company’s Board of Directors on May 24, 2018 and was approved by the Company’s stockholders on June 27, 2018.

Under the 2018 Plan, the Company may grant incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants, and advisors. The maximum aggregate number of shares of the Company’s common stock that may be issued under the 2018 Plan is 26,823.

The 2018 Plan was amended and restated following unanimous approval of the Company’s Board of Directors on April 24, 2019 and was approved by the Company’s shareholders on June 17, 2019. The amended 2018 Plan (the “Amended Plan”) allowed for an additional 39,300 shares of the Company’s common stock that may be issued under the Amended Plan with respect to awards made on and after June 17, 2019.

The 2021 Incentive Compensation Plan (the “2021 Plan”) was unanimously approved by the Company’s shareholders on July 30, 2021. Upon stockholders’ approval of the 2021 Plan, no further awards will be made under the amended 2018 Plan. Under the 2021 Plan, the Company may grant incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants, and advisors.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

The 2021 Plan was amended and restated following unanimous approval of the Company's Board of Directors on May 23, 2022 and was approved by the Company's shareholders on August 18, 2022. The amended 2021 Plan (the "Amended 2021 Plan") allowed for an additional 2,000,000 shares of the Company's common stock that may be issued under the Amended 2021 Plan with respect to awards made on and after August 18, 2022. At June 30, 2023, there were 1,276,885 shares available for future issuance.

Stock-based compensation expense includes stock options granted to employees and non-employees and has been reported in the Company's statements of operations and comprehensive loss in either research and development expenses or general and administrative expenses depending on the function performed by the optionee. No net tax benefits related to the stock-based compensation costs have been recognized since the Company's inception. The Company recognized stock-based compensation expense related to stock options and restricted stock units as follows for the three and six months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
General and administrative	$ 168,000	$ 72,000	$ 334,000	$ 259,000
Research and development	105,000	169,000	275,000	278,000
	$ 273,000	$ 241,000	$ 609,000	$ 537,000

A summary of stock option activity for the six months ended June 30, 2023 is as follows:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2022	1,397,763	$ 7.15	9.18	$ —
Granted	478,250	$ 0.75	10.00	—
Exercised	—	$ —	—	$ —
Forfeitures/adjustments	(164,216)	$ 1.92	9.10	
Balance, June 30, 2023	1,711,797	$ 5.11	8.71	$ —
Exercisable at June 30, 2023	460,431	$ 15.24	7.34	$ —

The Company accounts for all stock-based payments made to employees, non-employees and directors using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. Compensation expense is recognized for the portion that is ultimately expected to vest over the period during which the recipient renders the required services to the Company using the straight-line single option method.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, assumptions related to the expected price volatility of the Common Stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

As of June 30, 2023, there was $1,078,000 of unrecognized compensation expense related to the unvested stock options which is expected to be recognized over a weighted-average period of approximately 1.70 years.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

The weighted-average assumptions underlying the Black-Scholes calculation of grant date fair value of stock options include the following:

	Six months ended June 30,	
	2023	2022
Risk-free interest rate	3.63 %	2.01 %
Expected volatility	121.00 %	121.49 %
Expected term	5.85 years	5.85 years
Expected dividend yield	0 %	0 %
Weighted average grant date fair value	$ 0.64	$ 1.51

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the “simplified” method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.
- Expected stock price volatility: Expected volatility is based on the historical volatility of the Company’s Common Stock.
- Expected annual dividend yield: The Company has never paid, and does not expect to pay, dividends in the foreseeable future. Accordingly, the Company assumed an expected dividend yield of 0.0%.

On August 2, 2021, the compensation committee of the Board of Directors approved restricted stock unit grants to the Company’s employees (“2021 RSU”). An aggregate of 104,700 service-based RSUs were issued at a grant date fair value of $5.19. The 2021 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. The 2021 RSU awards were granted under the 2021 Plan. During the six months ended June 30, 2023, there were no vesting events, forfeitures, expirations, or cancelations of 2021 RSUs; there were forfeitures of 9,300 of the 2021 RSUs. On February 7, 2022, the compensation committee of the Board of Directors approved restricted stock unit grants to the Companies employees (“2022 RSU”). An aggregate of 148,343 service-based RSUs were issued at a grant date fair value of $1.82. The 2022 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. During the six months ended June 30, 2023, there was a vesting event for 43,567 of the 2022 RSUs. There were no forfeitures, expirations, or cancelations of the 2022 RSUs during the period; there were forfeitures of 11,667 of the 2022 RSUs. On June 10, 2022, the compensation committee of the Board of Directors approved restricted stock unit grants to certain of the Company’s employees (“2022 RSU2”). An aggregate of 24,200 service-based RSUs were issued at a grant date fair value of $1.33. The 2022 RSU2 awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. During the six months ended June 30, 2023, there were no vesting events expirations, or cancelations of the 2022 RSU2s. On March 13, 2023, the compensation committee of the Board of Directors approved restricted stock unit grants to the Companies employees (“2023 RSU”). An aggregate of 169,217 service-based RSUs were issued at a grant date fair value of $0.73. The 2023 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. During the six months ended June 30, 2023, there were no vesting events, expirations, or cancelations of the 2023 RSUs; there were forfeitures of 27,334 of the 2023 RSUs At June 30, 2023, the unrecognized compensation cost related to unvested service-based RSUs was $370,000, which will be recognized over the remaining service period.

Onconova Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

Grants of PSUs and SARs

During 2020 and 2021, the compensation committee of the Board of Directors and the board approved a cash bonus program of cash-settled stock appreciation right ("SAR") awards to the Company's employees and non-employee directors, and cash-settled performance stock unit ("PSU") awards to the Company's employees. These awards were granted outside of the 2018 Plan and the 2021 Plan. As the Company's stock price has decreased since these awards, their impact on the results of operations and balance sheet of the Company are not material during 2022 or 2023.

8. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University ("Temple"), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through June 30, 2023 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company.

9. Securities Registrations and Sales Agreements

August 2021 Equity Distribution Agreement

On August 20, 2021, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Piper Sandler & Co. ("Piper Sandler") under which the Company could offer and sell, from time to time at its sole discretion, shares of the Company's common stock, with aggregate gross sales proceeds of up to $25.0 million through an "at the market" equity offering program under which Piper Sandler was the sales agent. The Equity Distribution Agreement expired in May 2023.

Under the Equity Distribution Agreement, the Company had the right to set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitations on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Equity Distribution Agreement, Piper Sandler sold the shares by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made through The Nasdaq Capital Market or any other trading market for our common stock. The Equity Distribution Agreement provided that Piper Sandler was entitled to compensation for its services equal to 3.0% of the gross proceeds of any shares of common stock sold through Piper Sandler under the Equity Distribution Agreement. The Company had no obligation to sell any shares under the Equity Distribution Agreement, and could at any time suspend solicitation and offers under the Equity Distribution Agreement. Through June 30, 2023, the Company sold 109,523 shares under the agreement at a weighted average price of $5.32 per share. Net proceeds after commissions and offering expenses were approximately $0.5 million. There were no shares sold by the Company under the agreement during the six months ended June 30, 2023 and 2022.

The shares were issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-237844), which expired in May 2023. The Company filed a prospectus supplement, dated August 20, 2021 with the Securities and Exchange Commission in connection with the offer and sale of the shares pursuant to the Equity Distribution Agreement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with interim unaudited condensed consolidated financial statements contained in Part I, Item 1 of this quarterly report, and the audited consolidated financial statements and notes thereto for the year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the SEC on March 30, 2023. As used in this report, unless the context suggests otherwise, "we," "us," "our," "the Company" or "Onconova" refer to Onconova Therapeutics, Inc. and its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements. We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, protection of our intellectual property portfolio, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial and manufacturing functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, collaborations, partnerships, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this report, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

- our need for additional financing for our clinical-stage programs, continued product development and other operations, and our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;
- our ability to continue as a going concern;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;
- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies, for funding and commercialization of our clinical product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;

- our plans and ability to develop, manufacture and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- recently enacted and future legislation and regulation regarding the healthcare system;
- the success of competing therapies and products that are or become available;
- our ability to maintain the listing of our securities on a national securities exchange;
- the potential for third party disputes and litigation; and
- the performance of third parties, including contract research organizations ("CROs") and third-party manufacturers.

Any forward-looking statements that we make in this report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the "Risk Factors" in our most recent annual report on Form 10-K, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. We have proprietary molecularly targeted agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation. We believe that the product candidates in our pipeline have the potential to be efficacious in a variety of cancers with unmet medical need. We have the following two clinical-stage programs: 1. narazaciclib (ON 123300), a multi-targeted kinase inhibitor in solid tumors and hematological malignancies as a single agent or in combination with other anti-cancer therapies; and 2. rigosertib administered alone or in combination for the treatment of various cancers. We are currently evaluating compounds for in-licensing opportunities.

Our net losses were $10.0 million and $8.1 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $473.7 million. We expect to incur significant

expenses and operating losses for the foreseeable future as we continue the development of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met.

As of June 30, 2023, we had $29.7 million in cash and cash equivalents. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the second quarter of 2024; therefore, based on current projections, we do not have sufficient cash and cash equivalents as of the date of this report to support our operations for at least the 12 months following the date that these financial statements are issued. Accordingly, substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these financial statements are issued.

On August 20, 2021, we entered into an at-the-market equity distribution agreement for the sale of up to $25.0 million of common stock. The agreement expired in May 2023. Through June 30, 2023, we sold 109,523 shares under the agreement at a weighted average price of $5.32 per share. Net proceeds after commissions and offering expenses were approximately $0.5 million.

We are exploring various sources of funding for development and applying for regulatory approval of our research compounds as well as for our ongoing operations. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us. There can be no assurance, however, that we will be successful in obtaining such financing in sufficient amounts, on terms acceptable to us, or at all. In addition, there can be no assurance that we will obtain approvals necessary to market our product candidates or achieve profitability or sustainable, positive cash flow. If we are unable to successfully raise sufficient additional capital, through future financings or through strategic and collaborative arrangements, we will not have sufficient cash to fund our ongoing trials and operations.

Product Candidates / Compounds

Narazaciclib (ON 123300) — Differentiated Multi-Kinase Inhibitor Targeting CDK4/6

Pursuant to a license agreement with Temple University dated January 1, 1999 as amended March 21, 2013, we licensed compounds including our product candidate narazaciclib from Temple University. Narazaciclib is a multi-targeted kinase inhibitor targeting multiple cyclin-dependent kinases, (CDK's), AMP-activated protein kinase (AMPK) related protein kinase 5 (ARK5), and colony-stimulating factor 1 receptor (CSF1R) at low nM concentrations as well as other tyrosine kinases believed to drive tumor cell proliferation, survival and metastasis. As an apoptotic and antiproliferative agent, narazaciclib modulates the levels and activities of regulatory proteins of the cell cycle, including cyclin D1 and inhibits retinoblastoma (Rb) protein binding. Narazaciclib inhibits cancer cell growth and suppresses deoxyribonucleic acid (DNA) synthesis by preventing CDK-mediated G1-S phase transition, followed by tumor cell death by induction of mitochondria-mediated apoptosis. We believe, based on data from preclinical studies, that narazaciclib has the potential to overcome the limitations of the current generation of approved cyclin dependent kinase (CDK) 4/6 inhibitors. The below table depicts the half-maximal in vitro inhibitory concentration (IC50) of narazaciclib palbociclib, ribociclib and abemaciclib. IC50 is a quantitative measure indicating the concentration of each drug needed

to inhibit, in vitro, these listed kinases by 50%. We believe our CDK inhibitor is differentiated from other agents in the market or in development due to its multi-targeted kinase inhibition profile.

	Narazaciclib	**Palbociclib**	**Ribociclib**	**Abemaciclib**
Sponsor	Onconova	Pfizer	Novartis	Lilly
CDK Family				
CDK4/cyclin D1	2	2	3	0.8
CDK6/cyclin D1	0.6	0.8	6.0	0.6
CDK1/cyclin A	2190	>10,000	>10,000	270
CDK2/cyclin E	69	2300	>10,000	130
CDK9/T1	48	630	390	7
Other Kinases				
CSF1R	0.7	>10,000	>10,000	>10,000
ARK 5/NUAK 1	5	1,400	1,540	773
FLT3	6.0	496	753	72

Source: Reaction Biology 2021

In addition to CDK 4/6, narazaciclib also inhibits ARK5 (NUAK1) with high potency with a 50% inhibitory concentration (IC50) of 4.95 nM (Report EPR-123300-001 and Reddy 2014) while palbociclib, ribociclib, and abemaciclib do not. The equilibrium dissociation constant (Kd) value of narazaciclib binding to ARK5 was found to be 19 nM, while a known NUAK1 specific inhibitor (HTH-015-01) was 790 nM. In addition, using a cellular based assay that measures kinase activity in intact cells, NanoBret technology, it was determined that narazaciclib inhibited ARK5 with an IC50 value of 30 nM, while 2 published inhibitors, HTH-015-01 and WZ4003, had IC50 values of >10,000 nM. ARK5 (also known as NUAK1) is a member of the AMPK catalytic subunit family and functions as a key regulator of cellular energy homeostasis (Lui 2012). ARK5 has been shown to be important in a number of cancer cell regulated survival pathways such as regulating AKT dependent cell survival, cell metabolism through c-MYC activity, tumor cell survival under oxidative stress and tumor cell migration (Faisal, 2020, Lui, 2012, Port, 2018). The combination of CDK and ARK5 inhibitors in the same molecular entity is proposed to have a differentiated effect on cancer cells by simultaneously inhibiting both cell cycle (cytostatic) and cellular metabolism (cytotoxic) pathways through CDK and ARK5, respectively.

Narazaciclib also inhibits CSF1R with IC50 values between 0.7 to 10 nM (Unpublished data and Reddy 2014). The Kd value of narazaciclib binding to CSF1R was determined to be 0.7 nM. The ability of narazaciclib to bind and inhibit CSF1R at low nanomolar values, in both in vitro and cell-based assays suggests that this compound may have an impact in cancers with a dependence on CSF1R signaling.

Narazaciclib potently targets the protein BUB1. High levels of expression of BUB1is a prediction marker of core survival in breast cancer.

Narazaciclib’s potent antitumor activity against mantle cell lymphoma (MCL) cell lines, independent of their sensitivity to the FDA-approved Bruton’s tyrosine kinase inhibitor ibrutinib has been demonstrated in preclinical studies. Narazaciclib’s activity against MCL cell lines was shown to be superior to that of the FDA-approved CDK 4/6 inhibitors palbociclib and ribociclib, and similar to that of the FDA-approved CDK 4/6 inhibitor abemaciclib. Combining narazaciclib with ibrutinib led to synergistic increases in antitumor activity against both ibrutinib-sensitive and ibrutinib-resistant MCL cell lines. Preclinical data from this study was presented at the 17th International Conference on Malignant Lymphoma, in Lugano, Switzerland, on June 14, 2023.

In certain in vitro models, the kinase inhibitory profile of narazaciclib had high activity against CDK4, CDK6, ARK5, CSF1R, PDGFRß and PI3K-δ, all of which are associated with the growth, survival and metastasis of human tumor cells (Reddy, 2014). In an in vitro investigation of narazaciclib against a broad spectrum of human tumor cell lines, narazaciclib displayed potent antiproliferative activity, with 50% growth inhibitory concentrations (GI50) ranging from 0.02 µM to 1.5 µM. In these in vitro models, narazaciclib exhibited a broad range of activity against a wide spectrum of cell lines of both hematological origin (lymphoma, leukemia and myeloma) as well as solid tumors derived

from multiple organ sites. Studies on drug-resistant human tumor cell lines suggested that narazaciclib is not a multidrug resistance gene (mdr1) substrate and may be active against drug-resistant tumor cell lines (IBv.1 2020; Reddy, 2014). The activity of narazaciclib does not appear to be affected by the overexpression of MDR-1 and induced apoptosis in both ibrutinib-sensitive and ibrutinib-resistant patient derived cells (Divakar, 2016). The ability of narazaciclib to inhibit the CDK4/6/RB1 pathway has also been shown in pre-clinical testing of mantle cell lymphoma (Divakar, 2016), multiple myeloma (Perumal, 2016), various breast cancer subtypes (Reddy 2014) and colorectal cancer (IBv.2 2022).

The effectiveness of first-generation non-selective CDK inhibitors (Selicilib/roscovitine and Alvocidib/ flavopiridol) in early trials was limited due to toxicities (Blachly 2013). Second-generation compounds (palbociclib and ribociclib) specifically inhibit CDK4 and 6, thereby inhibiting retinoblastoma (RB) protein phosphorylation. Abemaciclib is a multi-targeted kinase CDK4/6 inhibitor with low nano molar activity against CDK4/6. The second generation CDK4/6 inhibitors have substantially improved clinical outcomes for patients with hormonal-receptor (HR) positive metastatic breast cancer (Hortobagyi 2018, Sledge 2017, Finn 2016). Several CDK4/6 inhibitors (palbociclib, ribociclib and abemaciclib) have been approved and are now standard of care either alone (abemaciclib) or in combination with anti-estrogen therapy for patients with HR-positive, HER2-negative metastatic breast cancer. Another CDK4/6 inhibitor has recently been approved, trilaciclib, in the supportive care space, for the prevention of myelosuppression following chemotherapy.

In December 2017, we entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. (HanX), a company focused on development of novel oncology products, for the manufacturing, clinical development, registration and commercialization in China of narazaciclib. Under the terms of the agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on any future Chinese sales if the drug is approved. The key feature of the 2017 collaboration was that HanX provided all funding required for the Chinese Investigational New Drug Application (IND) thereby enabling the studies necessary in order to seek IND approval by the National Medical Products Administration (the Chinese FDA). In the fourth quarter of 2019, HanX filed an IND with the Chinese FDA which was approved on January 6, 2020. We and HanX also intended for these studies underlying the Chinese IND approval, to meet the US Food and Drug Administration (FDA) standards for IND approval. Accordingly, such studies were used by us for an IND filing with the US FDA. In September 2020, a Phase 1 Study with narazaciclib in cancer patients was initiated in China. We maintain global rights to the manufacturing, clinical development and commercialization of narazaciclib outside of China.

In partnership with HanX, a Phase 1 dose escalation study (Study HX301-I-01) for patients with advanced relapsed/refractory cancer has been initiated in China at three sites and the first patient was enrolled on September 15, 2020. In this study HX301 (narazaciclib) is dosed every day for 21 days followed by 7 days off therapy in each 28 -day cycle. In China, the first four dose cohorts have been completed. The fifth cohort at 200 mg per day is ongoing on a three weeks-on followed by a one week-off schedule.

Our IND submission to the US FDA was submitted in November 2020 and the FDA Study May Proceed letter was issued in December 2020. Enrollment into the complementary US phase 1 study (Study 19-01) with narazaciclib commenced in May 2021. The study will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of narazaciclib administered orally at increasing doses starting at 40 mg daily for consecutive 28-day cycles in patients with relapsed/refractory advanced cancer. Enrollment in the fifth dose cohort (200 mg orally each day) of the Phase 1 solid tumor study of narazaciclib is complete with one dose limiting toxicity (DLT) observed. The sixth dose cohort (240 mg daily) is currently ongoing, with one DLT observed. In study 19-01 in the US narazaciclib is dosed on a continuous daily schedule.

Collectively, once completed, these two Phase 1 studies are expected to provide preliminary safety data and the recommended Phase 2 dose and schedule for narazaciclib as a single agent.

Retinoblastoma (Rb) protein is a master regulator of cell division and is critical to several cellular processes including senescence, self-renewal, replication and apoptosis (Engel, 2015). It is believed that loss or inactivation of Rb leads to malignant cell formation and occurs in the pathogenesis of some cancers. In a preclinical Rb positive xenograft model for breast cancer, narazaciclib activity was shown to be similar to palbociclib (Pfizer’s Ibrance ®). Moreover, based on the same preclinical model, narazaciclib may have the potential advantage of reduced neutropenia when

compared to palbociclib. Whereas both compounds resulted in decreased RBC and platelet counts in this preclinical model system, palbociclib was found to have a more prominent and statistically significant ($P< 0.01$) inhibitory effect on neutrophil counts when compared to narazaciclib. These results would need to be replicated in clinical trials.

In vitro studies compared the growth inhibitory activity of narazaciclib and palbociclib in breast cancer RB null cell lines, which demonstrated resistance to palbociclib while maintaining sensitivity towards narazaciclib (IBv.2 2022). Studies using mantle cell lymphoma cells indicated that narazaciclib was able to induce cell death via induction of apoptosis by inhibiting the AKT/PI3K/mTOR pathway while palbociclib treatment was only able to induce cell cycle arrest due to the inhibition of CDK4/6 (Divakar, 2016). Narazaciclib treatment was associated with the presence of several apoptotic markers (PARP, caspase 3, caspase 7 and caspase 9) and narazaciclib (but not palbociclib) led to the generation of apoptotic cells. Overall, apoptosis following narazaciclib exposure has been observed in the following cell lines: breast cancer (IBv.2 2022, Reddy, 2014), mantle cell lymphoma (Divakar, 2016), multiple myeloma (Perumal, 2016) and colorectal cancer (IBv.2 2022).

In addition to CDK4/6 and PI3 Kinase pathways, narazaciclib inhibits several other kinases in vitro including ARK5 (NUAK1) (IC50 of 4.95 nM) (IBv.2 2022, Reddy, 2014) while palbociclib does not. ARK5 is a member of the AMPK family and is thought to function as a key regulator of cellular energy homeo-stasis (Liu, 2012) and is important in a number of cancer cell survival pathways. Overexpression of ARK5 is associated with poor prognosis in hepatocellular cancer (Cui, 2013), ovarian cancer (Phippen, 2016), colorectal cancer (Port, 2018) and glioblastoma (Lu, 2013). ARK5 is involved in the increased invasiveness, migration and metastatic potential of breast cancer cells (Chang, 2012), colorectal cancer (Kusakai, 2004), gastric cancer (Chen, 2017), and multiple myeloma (Suzuki et al., 2005). Narazaciclib inhibits ARK5 which may result in down regulation of the mTOR/MYC/RB1 pathways leading to cell cycle arrest and apoptosis.

Because ARK5 activity is now recognized as a component in promoting cancer cell migration and invasion (Kusaki, 2004) the effect of narazaciclib treatment may have an impact on cell migration and metastasis. In certain in vitro models, narazaciclib was able to inhibit the percent migration of U87 cells in a concentration- dependent manner. The time and concentrations that were tested did not result in cell death but did inhibit cell division at the higher concentrations (IBv.2 2022). The ability of narazaciclib to inhibit cell migration was compared to palbociclib using a wound healing model. Triple negative cancer cell migration was inhibited for 72 hours in the presence of narazaciclib but not in the presence of palbociclib (IBv.2 2022).

The pathogenesis and progression of a number of cancers, including breast and multiple myeloma, is linked to C-Myc (Li, 2003) which was dependent on ARK5 activity (Liu, 2012) and calcium dependent metabolism (Monteverde, 2018). The inhibition of ARK5 has been shown to be lethal in MYC overexpressing tumors (Liu, 2012, Perumal, 2016) and targeting ARK5 in the inhibitory profile of narazaciclib has the potential to overcome the emergence of resistance to CDK4/6 inhibitors due to the loss of retinoblastoma function and C-Myc overexpression. Preclinical studies with tumor cell lines suggest that several malignancies including HR-positive breast cancer, colorectal carcinoma, hepatocellular carcinoma, mantle cell lymphoma and multiple myeloma, may be clinically responsive to narazaciclib exposure (Reddy, 2014, Divakar, 2016, Perumal, 2016). Furthermore, narazaciclib has been tested in four murine xenograft models (breast cancer, colorectal cancer, mantle cell lymphoma and multiple myeloma) and was found to have on-target activity and be non-toxic to the animals (Reddy, 2014; Divakar, 2016; Perumal, 2016; and IBv.2 2022).

CSF1R is in the class III kinase receptors that include c-Kit, platelet-derived growth factor receptor (PDGFR) alpha, and FLT3. CSF1R has 2 high affinity binding ligands, colony stimulating factor 1 (CSF-1), also known as macrophage colony-stimulating factor (M-CSF) and interleukin 34 (IL-34). CSF-1 is important for the differentiation and proliferation of myeloid progenitor cells into macrophages, monocytes, dendritic cells, and osteoclasts. Macrophages play an important role in the pathogenesis of not only tumor growth but multiple other diseases such as inflammatory diseases and bone metabolism. High levels of CSF-1 are critical for the recruitment of tumor associated macrophages (TAMs), predominantly the immunosuppressive phenotype (M2). They are the main inflammatory immune cells in the tumor microenvironment and are involved in tumor immunosuppression, angiogenesis, invasion, and metastasis.

Overexpression of CSF-1 or CSF1R is associated with tumor aggressiveness and poor prognosis. Inhibiting the signaling pathway of CSF1R provides a method to reduce the number of M2 macrophages/TAMs within the tumor

microenvironment and thus improve anti-tumor immunological therapy. Recent studies have found that CSF-1/CSF1R axis blockade can improve the efficiency of immune checkpoint inhibitors, especially programmed death-ligand 1 inhibitors.

Cancer cells can lose RB function through mutation and become resistant or insensitive to palbociclib. Generally, second generation agents have not been shown to be suitable for single agent therapy and must typically be used in combination with hormonal therapy in the treatment of HR+/HER2- mBC. In addition, the rate of disease progression that occurs, especially in patients with visceral disease (Hortobagyi 2018), may benefit from the novel inhibitory effects of narazaciclib. This hypothesis needs to be proven in a clinical trial.

Unfortunately, several mechanisms of acquired resistance are emerging with the approved CDK4/6 inhibitors leading to progression in patients with HR+/HER2- mBC (Spring, 2019; Knudsen, 2020). Therefore, the unmet medical need supports development of the next (third) generation CDK4/6 inhibitors in advanced HR+/HER- mBC. The inhibitory effect of narazaciclib may provide a therapeutic strategy to optimize efficacy of CDK 4/6 inhibition and reduce the emergence of resistance and/or provide clinical benefit for patients with progression on palbociclib, ribociclib and/or abemaciclib.

We believe narazaciclib has a favorable kinase inhibitory profile in comparison to the approved CDK4/6 inhibitors (palbociclib, ribociclib, and abemaciclib) and may result in both tumorigenic and safety benefits (Perumal, 2016, Divakar, 2016).

Based on data from continuous dosing studies in rats and monkeys the safety profile of narazaciclib is anticipated to be better than the approved CDK4/6 inhibitors with myelosuppression and gastrointestinal toxicity being most common. Management of these adverse events is expected to follow that used for the approved CDK 4/6 inhibitors. We believe that the proposed mechanism of action of narazaciclib, the unmet medical need of the advanced cancers potentially targeted by narazaciclib and the anticipated safety profile of narazaciclib as seen in pre-clinical studies, support conducting clinical studies.

Clinical development of narazaciclib for breast cancer as well as other solid tumors and hematological malignancies in clinical trials is warranted based on the preclinical in vitro studies as well as the xenograft models. Onconova plans to advance testing whether narazaciclib will demonstrate activity and/or safety in patients with advanced malignancies.

As previously mentioned, CDK 4/6 inhibitors have been added to aromatase inhibitors and SERDs to enhance anti-tumor activities in HR+, HER2- metastatic breast cancer. Mirza and colleagues presented the results of the randomized phase 2 study NSGO-PALEO / ENGOT-EN3 trial at ESMO 2020 and reported that palbociclib and letrozole yielded meaningful PFS benefit in women with ER+ recurrent endometrial cancer (Mirza et al. 2020).

Endometrial carcinoma (EC) is the most common gynecological malignancy (American Cancer Society 2021). Endometrioid endometrial carcinoma (EEC), the most common subtype of EC, accounts for approximately 75% of cases. In the US, approximately 65,950 new endometrial cancers and uterine sarcomas and approximately 12,550 deaths are expected in 2022, and the incidence and mortality have been increasing (American Cancer Society 2022). Low-grade (Grade 1 or 2) EECs (LGEECs) have ≥95% (Grade 1) or 50% to 94% (Grade 2) cancer tissue forming glands. Treatment includes surgery, radiotherapy, and/or systemic therapy. Systemic therapy is typically chemotherapy and/or hormonal therapy, and typical regimens include paclitaxel/carboplatin with letrozole maintenance; paclitaxel/carboplatin/bevacizumab with bevacizumab maintenance; or letrozole, anastrozole, or exemestane (NCCN 2022). Overall, five-year disease-free survival and five-year survival are high, 81.7% and 83.1%, respectively (Gottwald 2010), but for recurrent or metastatic disease morbidity and mortality are high.

In the NSGO-PALEO / ENGOT-EN3 trial presented by Mirza at ESMO 2020 participants were randomized to letrozole 2.5 mg orally D1-28 with either palbociclib 125 mg or placebo orally d1–21 in a 28-d cycle until disease progression. PFS was significantly improved with letrozole and palbociclib compared to the placebo arm (median PFS 8.3 vs. 3.0 months, HR 0.56, 95% CI 0.32 to 0.98, p=0.04). Disease control rate at 24 weeks was also improved (63.6% vs. 37.8%). This data has been reinforced by phase 2 data presented with ribociclib and letrozole as well as abemaciclib and letrozole in this patient population.

Onconova initiated a multi-center Phase 1/2a trial evaluating its multi-kinase inhibitor, narazaciclib, in combination with letrozole as a second- or third-line therapy for the treatment of recurrent metastatic low-grade endometrioid endometrial cancer (LGEEC) in 1Q23. Both narazaciclib and letrozole will be administered orally with a continuous daily dosing schedule in the trial, which will begin with a Phase 1 dose escalation phase before moving to a Phase 2 expansion cohort designed to enroll approximately 30 patients. The first patient in this trial was dosed in May 2023.

Oral Rigosertib and PD-1 Combination in KRAS-Mutated Cancers

We are currently supporting an investigator-initiated study (IIS) that is exploring the use of oral rigosertib for cancers driven by mutated K-Ras genes, a Phase 1/2a study of rigosertib in combination with a PD-1 inhibitor (nivolumab) for patients with check point inhibitor (CPI) resistant K-Ras mutated non-small cell lung cancer (NSCLC). The NSCLC study is open and continues to enroll patients. The objectives of this study are to identify the recommended Phase 2 dose (RP2D) of the combination for future studies and characterize the safety profile of the combination treatment. To date, one patient with a DLT of hyponatremia has been observed. Continued dose escalation is being planned. At the current dose level, the maximum tolerated dose does not appear to have been reached. Interim data presented at the European Society of Medical Oncology (ESMO) meeting in September 2022 showed an early and encouraging signal of efficacy in the trial's extensively pre-treated population, with one complete response, two partial responses, and one instance of stable disease achieved in fourteen evaluable patients. These responses were achieved in patients with three distinct KRAS mutations who had failed prior checkpoint inhibitor therapy, thereby confirming rigosertib's KRAS-agnostic mechanism of action and potential to synergize with anti-PD-1 agents. We believe this supports further investigation of rigosertib in combination with CPI in KRAS mutated NSCLC. Additional data from this trial will be presented at a future medical meeting.

On June 17, 2021, we announced a publication in Molecular Cancer (Yan, C., Saleh, N., Yang, J. *et al.* Novel induction of CD40 expression by tumor cells with RAS/RAF/PI3K pathway inhibition augments response to checkpoint blockade. *Mol Cancer* **20,** 85; 2021) which demonstrated that rigosertib synergistically combined with a CPI improved tumor growth inhibition and survival in a murine melanoma model that did not respond to a CPI alone. It was postulated that rigosertib's anti-cancer activity was due to its ability to reverse immunosuppressive tumor microenvironments. We believe this pre-clinical data support the clinical evaluation of rigosertib in combination with a CPI in metastatic melanoma that has progressed on CPI therapy. An IIS at Vanderbilt University evaluating oral rigosertib in combination with pembrolizumab in patients with CPI resistant advanced/metastatic melanoma was opened for enrollment in March 2023 and continues to enroll patients.

Rigosertib as monotherapy

RDEB is an ultra-rare condition with high unmet medical need caused by a lack of type VII collagen protein expression. Type VII collagen protein is responsible for anchoring the skin's inner layer to its outer layer, and its absence leads to extreme skin fragility and chronic wound formation in RDEB patients. Over time, many of these patients develop squamous cell carcinomas (SCCs) that typically arise in areas of chronic skin wounding and inflammation. Preclinical investigations demonstrated overexpression of polo like kinase 1 (PLK1) in RDEB-associated SCC tumor cells. These tumors show a highly aggressive, early metastasizing course, making them the primary cause of death for these patients, with a cumulative risk of death of 70% and 78.7% by age 45 and 55, respectively (Mellerio, 2016), (Fine, 2016). These neoplasms show limited response rates of mostly short duration to conventional chemo- and radiotherapy as well as targeted therapy with epidermal growth factor and tyrosine kinase inhibitors (Mellerio, 2016), (Stratigos, 2020).

Based on rigosertib's activity as a potent PLK-1 pathway inhibitor (Atanasova, 2019), a Phase 2 open label IIS with rigosertib monotherapy in patients with advanced/metastatic squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-SCC) is enrolling patients. As we disclosed in December 2021 early preliminary data from this study were presented at the Austrian Society of Dermatology and Venerology Annual Conference 2021, which took place from November 25 – 27, 2021 and at the World Congress on Rare Skin Diseases which took place in Paris, from June 7-9, 2022. More recently data was presented at the International Society of Investigative Dermatology (ISID) International Epidermolysis Bullosa Symposium in Osaka, Japan on May 9, 2023 and at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on June 3, 2023.

Data from the recent presentations are from a patient with a history of multiple, unresectable cutaneous SCCs (cSCC) that were unresponsive to prior treatments including cemiplimab. Results showed that intravenously administered rigosertib had an acceptable safety profile and that the patient experienced sustained clinical and histological complete remission of all lesions without signs of metastatic disease following 13 treatment cycles. The patient remained in complete remission for 16 months, at which time rigosertib administration was stopped due to disease recurrence. Another patient was recently enrolled, a patient with RDEB and multiple cSCCs and metastatic disease involving the lymph nodes whose prior treatments included surgical excision, systemic targeted therapy (cetuximab) and immunotherapy (pembrolizumab). At baseline, the patient had extensive, unresectable cSCC involving the left elbow region as well as nodal disease noted on PET-CT scan. After 4 cycles of oral rigosertib starting at 560 mg PO BID, there was reportedly complete clinical remission of all cSCC lesions. The patient has tolerated oral rigosertib and remains on therapy.

Although the trial's currently available safety and efficacy data are from only two patients, the investigators believe they represent a very encouraging finding that warrants further study. In addition, the investigators, and we, believe the data generated in preclinical models that suggest rigosertib's activity against PLK1 have now been preliminarily supported in the clinic and suggest that rigosertib may play a role in other more common cancers driven by PLK1. On June 27, 2023, Onconova and the investigators leading the ISS in RDEB-SCC met with the FDA to discuss the future development of rigosertib in this indication. Based on that meeting and the clinical responses in previously refractory patients we have seen and presented at major medical meetings, we plan to design a registrational trial.

Rare Disease Program in "RASopathies"

Preclinical studies with rigosertib are also being conducted in cardiomyopathies which are seen in children with RASopathies. Rigosertib normalized and reversed RASopathy-associated hypertrophic cardiomyopathy (HCM) as well as other syndromic features in Raf1L613V/+ mice.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our interim unaudited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, deferred revenue and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no significant changes in our critical accounting policies and estimates as discussed in our annual report on Form 10-K filed with the SEC on March 30, 2023.

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

	Three Months Ended June 30,		
	2023	2022	Change
Revenue	$ 57,000	$ 57,000	$ —
Operating expenses:			
General and administrative	2,211,000	2,139,000	(72,000)
Research and development	2,456,000	2,038,000	(418,000)
Total operating expenses	4,667,000	4,177,000	(490,000)
Loss from operations	(4,610,000)	(4,120,000)	(490,000)
Other income, net	360,000	96,000	264,000
Net loss	$ (4,250,000)	$ (4,024,000)	$ (226,000)

Revenues

Revenues for 2023 were consistent with 2022, and were due to the recognition of deferred revenue from our collaboration with SymBio.

General and administrative expenses

General and administrative expenses increased $0.1 million, or 3%, to $2.2 million for the three months ended June 30, 2023 from $2.1 million for the three months ended June 30, 2022. This increase was caused by $0.2 million increase in professional and consulting fees. These increases were partially offset by $0.2 million lower corporate insurance costs.

The details of our general and administrative expenses are:

	Three Months Ended June 30,	
	2023	2022
Professional & consulting fees	$ 496,000	$ 417,000
Stock based compensation	168,000	72,000
Personnel related	869,000	919,000
Public company costs	403,000	372,000
Insurance & other	275,000	359,000
	$ 2,211,000	$ 2,139,000

Research and development expenses

Research and development expenses increased by $0.4 million, or 21%, to $2.4 million for the three months ended June 30, 2023 from $2.0 million for the three months ended June 30, 2022. This increase was caused primarily by a $0.6 million increase in clinical development and consulting expenses related to narazaciclib and $0.1 million in higher manufacturing costs related to the timing of narazaciclib drug substance and drug product manufacturing. These increases were partially offset by $0.3 million lower personnel costs due to lower headcount in the 2023 period.

The details of our research and development expenses are:

	Three Months Ended June 30,	
	2023	2022
Preclinical & clinical development	$ 1,099,000	$ 574,000
Personnel related	383,000	645,000
Manufacturing, formulation & development	406,000	272,000
Stock based compensation	105,000	169,000
Consulting fees	463,000	378,000
	$ 2,456,000	$ 2,038,000

Other income, net

Other income, net, was income of $0.4 million and $0.1 million for the three months ended June 30, 2023 and 2022, respectively. The change was due to $0.3 million higher interest income partially offset by $23,000 higher foreign currency exchange loss in the 2023 period.

Comparison of the Six months ended June 30, 2023 and 2022

	Six Months Ended June 30,		
	2023	2022	Change
Revenue	$ 113,000	$ 113,000	$ —
Operating expenses:			
General and administrative	4,324,000	4,325,000	1,000
Research and development	6,536,000	4,040,000	(2,496,000)
Total operating expenses	10,860,000	8,365,000	(2,495,000)
Loss from operations	(10,747,000)	(8,252,000)	(2,495,000)
Other income, net	722,000	106,000	616,000
Net loss	$ (10,025,000)	$ (8,146,000)	$ (1,879,000)

Revenues

Revenues for 2023 were consistent with 2022, and were due to the recognition of deferred revenue from our collaboration with SymBio.

General and administrative expenses

General and administrative expenses were $4.3 million for the six months ended June 30, 2023, which was comparable to $4.3 million for the six months ended June 30, 2022. Professional and consulting fees increased $0.2 million in the 2023 period, which was offset by decreased personnel related and insurance costs in the 2023 period.

The details of our general and administrative expenses are:

	Six Months Ended June 30,	
	2023	2022
Professional & consulting fees	$ 995,000	$ 893,000
Stock based compensation	334,000	259,000
Personnel related	1,778,000	1,916,000
Public company costs	686,000	563,000
Insurance & other	531,000	694,000
	$ 4,324,000	$ 4,325,000

Research and development expenses

Research and development expenses increased by $2.5 million, or 62%, to $6.5 million for the six months ended June 30, 2023 from $4.0 million for the six months ended June 30, 2022. This increase was caused primarily by a $1.7 million increase in clinical development and consulting expenses related to narazaciclib and $0.9 million in higher manufacturing costs related to the timing of narazaciclib drug substance and drug product manufacturing. This increase was partially offset by $0.1 million lower personnel costs in the 2023 period.

The details of our research and development expenses are:

	Six Months Ended June 30,	
	2023	2022
Preclinical & clinical development	$ 2,415,000	$ 811,000
Personnel related	1,122,000	1,228,000
Manufacturing, formulation & development	1,882,000	1,020,000
Stock based compensation	275,000	278,000
Consulting fees	842,000	703,000
	$ 6,536,000	$ 4,040,000

Other income, net

Other income, net, was income of $0.7 million and $0.1 million for the six months ended June 30, 2023 and 2022, respectively. The change was due to $0.7 million higher interest income partially offset by $43,000 higher foreign currency exchange loss in the 2023 period.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $10.0 million and $8.1 million for the six months ended June 30, 2023 and 2022, respectively. Our operating activities used $9.0 million and $8.5 million of net cash during the six months ended June 30, 2023 and 2022, respectively. At June 30, 2023, we had an accumulated deficit of $473.7 million, working capital of $21.8 million, and cash and cash equivalents of $29.7 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and business operations into the second quarter of 2024; therefore, based on current projections, we do not have sufficient cash and cash equivalents as of the date of this Form10-Q filing to support our operations for at least the 12 months following the date that these financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern through the one-year period after the date that the financial statements are issued. Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, we may have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us.

We will require substantial additional financing to fund our ongoing clinical trials and operations, and to continue to execute our strategy. To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to explore various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon our ability to obtain additional funding. There can be no assurance, however, that we will be successful in obtaining such funding in sufficient amounts, on terms acceptable to us, or at all. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition. Accordingly, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these financial statements are issued.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (9,033,000)	$ (8,510,000)
Effect of foreign currency translation	5,000	(27,000)
Net (decrease) increase in cash and cash equivalents	$ (9,028,000)	$ (8,537,000)

Net cash used in operating activities

Net cash used in operating activities was $9.0 million for the six months ended June 30, 2023 and consisted primarily of a net loss of $10.0 million, including $0.6 million of noncash stock-based compensation expense. Changes in operating assets and liabilities resulted in a net increase in cash of $0.4 million. Significant changes in operating assets and liabilities included an increase in accounts payable of $1.2 million and a decrease in accrued liabilities of $0.6 million due to timing of invoices and payments to our vendors, an increase in prepaid expenses and other current assets

of $0.1 million, and a decrease in deferred revenue of $0.1 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in operating activities was $8.5 million for the six months ended June 30, 2022 and consisted primarily of a net loss of $8.2 million, including $0.5 million of noncash stock-based compensation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $0.9 million. Significant changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of $1.2 million, an increase in accounts payable of $0.3 million and decrease in accrued liabilities of $0.1 million due to timing of invoices and payments to our vendors, and a decrease in deferred revenue of $0.1 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Material Cash Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect net cash expended in 2023 to be higher than 2022 due to clinical trials with narazaciclib and increased headcount in our clinical and regulatory groups. We also expect an increase in costs for potential in-licensing, the timing of which will be determined by the timing of any potential in-licensing. We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that, currently, our non-cancelable obligations under these agreements are not material. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the second quarter of 2024; therefore, based on current projections, we do not have sufficient cash and cash equivalents to support our operations for at least the 12 months following the date that these financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern through the one-year period after the date that the financial statements are issued.

We are exploring various sources of funding for continued development of narazaciclib and any potential in-licensed compounds as well as our ongoing operations. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met. If we obtain regulatory approval for any of our product candidates, we expect to incur significant NDA preparation and commercialization expenses. We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic or collaborative partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States for any of our product candidates that achieve regulatory approval, such commercial infrastructure could be expected to include a targeted, oncology sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to having any certainty about marketing approval. Furthermore, we have and expect to continue to incur additional costs associated with operating as a public company.

For additional risks, please see “Risk Factors” in Part II of this report and previously disclosed in our most recent annual report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, the Company is not required to provide the information otherwise required by this Item.

Item 4. Controls and Procedures

Managements' Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of June 30, 2023, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are not party to any pending material legal proceedings and are not aware of any such proceedings contemplated by governmental authorities.

Item 1A. Risk Factors

In addition to the following risk factor, you should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the SEC on March 30, 2023 which could materially affect our business, financial condition or future results. The following risk factor and the risks described in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

We may not comply with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our Common Stock could be delisted, which could affect our Common Stock's market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests to maintain the listing of our securities on The Nasdaq Capital Market (Nasdaq). As of August 14, 2023, we were in compliance with the Nasdaq continued listing requirements; however, at certain times during 2023, 2022, 2021, and 2020 we were not in compliance with the Nasdaq continued listing requirements related to minimum bid price. The closing price of our stock on August 11, 2023 was $0.96. At certain times during 2019 and 2018 we were not in compliance with the Nasdaq continued listing requirements related to minimum stockholders' equity.

There can be no assurance that we will be able to maintain compliance with Nasdaq listing criteria. If we are unable to maintain compliance with the continued listing requirements of Nasdaq, our common stock could be delisted, making it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair our ability to raise capital.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File -The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ONCONOVA THERAPEUTICS, INC.

Dated: August 14, 2023

/s/ STEVEN M. FRUCHTMAN, M. D.
Steven M. Fruchtman, M.D.
President and Chief Executive Officer
(*Principal Executive Officer*)

Dated: August 14, 2023

/s/ MARK GUERIN
Mark Guerin
Chief Operating Officer and Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven Fruchtman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Onconova Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 14, 2023

/s/ Steven M. Fruchtman, M.D.
Steven M. Fruchtman, M.D.
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Guerin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Onconova Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 14, 2023

/s/ Mark Guerin

Mark Guerin
Chief Operating Officer & Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven Fruchtman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2023

/s/ Steven M. Fruchtman, M.D.
Steven M. Fruchtman, M.D.
President and Chief Executive Officer
(*Principal Executive Officer*)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Guerin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2023

/s/ Mark Guerin
Mark Guerin
Chief Operating Officer & Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.