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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 March 31, 2022

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 May 2, 2022 was 20,895,563.

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 MARCH 31, 2022

All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective May 20, 2021.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Onconova Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2022	December 31, 2021
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 50,767,000	$ 55,070,000
Receivables	27,000	28,000
Prepaid expenses and other current assets	583,000	332,000
Total current assets	51,377,000	55,430,000
Property and equipment, net	35,000	38,000
Other non-current assets	10,000	10,000
Total assets	$ 51,422,000	$ 55,478,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,122,000	$ 2,757,000
Accrued expenses and other current liabilities	2,600,000	3,132,000
Deferred revenue	226,000	226,000
Total current liabilities	5,948,000	6,115,000
Deferred revenue, non-current	3,187,000	3,243,000
Total liabilities	9,135,000	9,358,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.01 par value, 125,000,000 shares authorized, 20,895,563 shares issued and outstanding at March 31, 2022 and December 31, 2021	209,000	209,000
Additional paid in capital	490,940,000	490,644,000
Accumulated deficit	(448,841,000)	(444,719,000)
Accumulated other comprehensive loss	(21,000)	(14,000)
Total stockholders' equity	42,287,000	46,120,000
Total liabilities and stockholders' equity	$ 51,422,000	$ 55,478,000

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	2021
Revenue	$ 56,000	$ 56,000
Operating expenses:		
General and administrative	2,186,000	2,217,000
Research and development	2,002,000	1,937,000
Total operating expenses	4,188,000	4,154,000
Loss from operations	(4,132,000)	(4,098,000)
Change in fair value of warrant liability	—	(636,000)
Other income, net	10,000	19,000
Net loss	$ (4,122,000)	$ (4,715,000)
Net loss per share, basic and diluted	$ (0.20)	$ (0.32)
Basic and diluted weighted average shares outstanding	20,904,085	14,616,139

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (4,122,000)	$ (4,715,000)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustments, net	(7,000)	(16,000)
Other comprehensive loss, net of tax	(7,000)	(16,000)
Comprehensive loss	$ (4,129,000)	$ (4,731,000)

See accompanying notes to condensed consolidated financial statements.

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

	Three Month Periods Ended March 31, 2022 and 2021					
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total
	Shares	Amount				
Balance at December 31, 2021	20,895,563	$ 209,000	$ 490,644,000	$ (444,719,000)	$ (14,000)	$ 46,120,000
Net loss	—	—	—	(4,122,000)	—	(4,122,000)
Other comprehensive loss	—	—	—	—	(7,000)	(7,000)
Stock-based compensation	—	—	296,000	—	—	296,000
Balance at March 31, 2022	20,895,563	$ 209,000	$ 490,940,000	$ (448,841,000)	$ (21,000)	$ 42,287,000
Balance at December 31, 2020	12,396,219	$ 124,000	$ 434,593,000	$ (428,556,000)	$ 14,000	$ 6,175,000
Net loss	—	—	—	(4,715,000)	—	(4,715,000)
Other comprehensive loss	—	—	—	—	(16,000)	(16,000)
Exercise of stock options	2,867	—	17,000	—	—	17,000
Stock-based compensation	—	—	65,000	—	—	65,000
Issuance of common stock, net	3,220,075	32,000	35,115,000	—	—	35,147,000
Issuance of common stock upon exercise of warrants	160,000	2,000	478,000	—	—	480,000
Balance at March 31, 2021	15,779,161	$ 158,000	$ 470,268,000	$ (433,271,000)	$ (2,000)	$ 37,153,000

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	2021
Operating activities:		
Net loss	$ (4,122,000)	$ (4,715,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,000	3,000
Change in fair value of warrant liabilities	—	636,000
Stock compensation expense	296,000	65,000
Changes in assets and liabilities:		
Receivables	1,000	(1,000)
Prepaid expenses and other current assets	(251,000)	115,000
Accounts payable	365,000	(845,000)
Accrued expenses and other current liabilities	(532,000)	(1,850,000)
Deferred revenue	(56,000)	(56,000)
Net cash used in operating activities	(4,296,000)	(6,648,000)
Financing activities:		
Proceeds from the sale of common stock and warrants, net of costs	—	35,147,000
Proceeds from the exercise of common warrants	—	480,000
Proceeds from the exercise of stock options	—	17,000
Net cash provided by financing activities	—	35,644,000
Effect of foreign currency translation on cash	(7,000)	(16,000)
Net increase (decrease) in cash and cash equivalents	(4,303,000)	28,980,000
Cash and cash equivalents at beginning of period	55,070,000	19,025,000
Cash and cash equivalents at end of period	$ 50,767,000	$ 48,005,000

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 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 2. oral rigosertib alone or in combination with PD-1 inhibitors for treatment of KRAS-mutated solid tumors. During 2012, Onconova Europe GmbH was established as a wholly owned subsidiary of the Company for the purpose of further developing business in Europe.

On May 20, 2021, the Company amended its certificate of incorporation to decrease the number of authorized shares of common stock par value $0.01 per share from 250,000,000 to 125,000,000, and to effect a one-for-fifteen reverse stock split of its common stock. All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect this one-for-fifteen reverse stock split.

Liquidity

The Company has incurred recurring operating losses since inception. For the three months ended March 31, 2022, the Company incurred a net loss of $4,122,000 and as of March 31, 2022 the Company had generated an accumulated deficit of $448,841,000. 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 March 31, 2022, the Company had cash and cash equivalents of $50,767,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding. The Company is exploring 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 Company believes that its cash and cash equivalents will be sufficient to fund its ongoing trials and business operations for more than twelve months from the date of this filing.

COVID-19

While the Company is not aware of a material impact from the novel coronavirus disease ("COVID-19") pandemic through March 31, 2022, the full extent to which COVID-19 will directly or indirectly impact the Company's business, results of operations and financial condition, including manufacturing, clinical trials and research and development costs, depends on future developments that are uncertain at this time.

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 March 31, 2022, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2022 and 2021, the consolidated statements of stockholders' equity (deficit) for the three months ended March 31, 2022 and 2021 and the condensed consolidated statements of cash flows for the three months ended March 31, 2022 and 2021 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 March 31, 2022, the results of its operations for the three months ended March 31, 2022 and 2021, and its cash flows for the three months ended March 31, 2022 and 2021. The financial data and other information disclosed in these notes related to the three months ended March 31, 2022 and 2021 are unaudited. The results for the three months ended March 31, 2022 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, 2021 included in the Company's annual report on Form 10-K filed with the SEC on March 21, 2022.

All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective May 20, 2021.

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.

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2021 included in the Company's annual report on Form 10-K filed with the SEC on March 21, 2022. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

Fair Value Measurements

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. The fair value of the warrant liability is discussed in Note 7, "Fair Value Measurements."

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

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 is effective for the Company in fiscal years beginning after December 15, 2022, and interim periods within those years, with early adoption permitted. The guidance is not expected to have a material effect on the Company.

3. Revenue

The Company's revenue during the three months ended March 31, 2022 and 2021 was from its license and collaboration agreement with SymBio.

	Three Months Ended March 31,	
	2022	2021
Symbio		
Upfront license fee recognition over time	$ 56,000	$ 56,000

Deferred revenue is as follows:

	Symbio Upfront Payment
Deferred balance at December 31, 2021	$ 3,469,000
Recognition to revenue	(56,000)
Deferred balance at March 31, 2022	$ 3,413,000

4. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at March 31, 2022 and 2021 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):

	March 31,	
	2022	2021
Warrants	491,586	512,202
Stock options	871,842	43,026
	1,363,428	555,228

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.

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

Warrants outstanding and warrant activity (reflects the number of common shares as if the warrants were converted to common stock) for the three months ended March 31, 2022 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2021	Warrants Issued	Warrants Exercised	Warrants Expired	Balance March 31, 2022
Non-tradable pre-funded warrants	Equity	$ 2.25	July 2023	26	—	—	—	26
Non-tradable warrants	Equity	$ 24.00	December 2022	26,189	—	—	—	26,189
Non-tradable pre-funded warrants	Equity	$ 2.25	none	3,522	—	—	—	3,522
Non-tradable warrants	Equity	$ 24.00	December 2022	120,407	—	—	—	120,407
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
				500,108	—	—	—	500,108

6. Balance Sheet Detail

Prepaid expenses and other current assets:

	March 31, 2022	December 31, 2021
Research and development	$ 18,000	$ 15,000
Manufacturing	4,000	29,000
Insurance	255,000	253,000
Other	306,000	35,000
	$ 583,000	$ 332,000

Property and equipment:

	March 31, 2022	December 31, 2021
Property and equipment	$ 70,000	$ 70,000
Accumulated depreciation	(35,000)	(32,000)
	$ 35,000	$ 38,000

Accrued expenses and other current liabilities:

	March 31, 2022	December 31, 2021
Research and development	$ 1,765,000	$ 1,759,000
Employee compensation	727,000	1,217,000
Professional fees	108,000	156,000
	$ 2,600,000	$ 3,132,000

7. Fair Value Measurements

At both March 31, 2022 and December 31, 2021, the Company had no financial assets and liabilities measured at fair value on a recurring basis.

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

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.

During 2021, the Company had tradable warrants and non-tradable warrants that were classified as liabilities and measured at fair value on a recurring basis. The tradable warrants were listed on the Nasdaq Capital Market. The Company determined that an active and orderly market for the tradable warrants developed and that the Nasdaq Capital Market price was the best indicator of fair value of the warrant liability. The quoted market price was used to determine the fair value. The fair value of the non-tradable warrants was estimated using the Black-Scholes pricing model. All of these tradable and non-tradable warrants expired in July 2021. During the three months ended March 31, 2021, there was an increase in the fair value of the warrant liability of $636,000.

8. 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. The maximum aggregate number of shares of the Company's common stock that may be issued under the 2021 Plan is 1,300,000. At March 31, 2022, there were 230,215 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

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

Company recognized stock-based compensation expense related to stock options and restricted stock units as follows for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
General and administrative	$ 187,000	$ 56,000
Research and development	109,000	9,000
	$ 296,000	$ 65,000

A summary of stock option activity for the three months ended March 31, 2022 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, 2021	452,999	$ 20.71	9.42	$ —
Authorized	—			
Granted	418,125	$ 1.82	9.86	—
Exercised	—	$ —	—	$ —
Forfeitures/adjustments	718	$ 13,792.50	—	
Balance, March 31, 2022	871,842	$ 11.64	9.50	$ 8,362.50
Exercisable at March 31, 2022	32,874	$ 218.85	7.25	$ —

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 March 31, 2022, there was $1,986,000 of unrecognized compensation expense related to the unvested stock options which is expected to be recognized over a weighted-average period of approximately 2.38 years.

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

	Three months ended March 31,	
	2022	2021
Risk-free interest rate	1.80 %	0.62 %
Expected volatility	121.76 %	124.67 %
Expected term	5.85 years	6.25 years
Expected dividend yield	0 %	0 %
Weighted average grant date fair value	$ 1.58	$ 3.75

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

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. There were no vesting events, expirations, forfeitures, or cancelations of the 2021 RSUs during the period. 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. The 2021 RSU and 2022 RSU awards were granted under the 2021 Plan. There were no vesting events, expirations, forfeitures, or cancelations of the 2021 RSU or 2022 RSU during the period. At March 31, 2022, the unrecognized compensation cost related to unvested service-based RSUs was $681,000, which will be recognized over the remaining service period. During the three months ended March 31, 2022, the Company recognized $57,000 of stock-based compensation expense related to the 2021 RSU and 2022 RSU awards, which is included in additional paid-in capital.

Grants of PSUs and SARs

On July 9, 2020, the compensation committee of the board of directors and the board approved a cash bonus program of cash-settled stock appreciation right ("2020 SAR") awards and cash-settled performance stock unit ("2020 PSU") awards to the Company's employees. An aggregate of 2020 SAR awards with respect to 256,713 shares of common stock and 2020 PSU awards with respect to 124,220 shares of common stock were granted to the Company's employees. The 2020 SAR awards will be settled in cash, vest 33% on the first anniversary of the date of grant, and the remaining 67% monthly over the next 24 months, have a per-share base amount of $8.40, which was the closing sales price of a share of the Company's common stock on the grant date, and are in all cases subject to the terms and conditions of the Company's form of SAR award agreement. The 2020 SAR awards are cash-settled and were granted outside of the 2018 Plan and the 2021 Plan.

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

The 2020 PSU awards vest 50% upon the submission of a new drug application ("NDA") to the U.S. FDA for rigosertib in higher-risk myelodysplastic syndromes ("HR-MDS") and 50% upon U.S. FDA approval of rigosertib for HR-MDS. The 2020 PSU awards have a maximum value of $21.60 per share. The maximum price per share is the per-share value based on the Company's market capitalization at $250 million and the Company's outstanding shares of common stock, which was 11,611,829 shares on July 9, 2020. In all cases, the 2020 PSU awards are subject to the terms and conditions of the Company's form of PSU award agreement. The 2020 PSU awards are cash-settled and were granted outside of the 2018 Plan and the 2021 Plan.

In addition, on July 9, 2020, based on the recommendation of the compensation committee, the board approved a change in the non-employee director compensation policy that would provide for an annual SAR award ("2020 Director SAR") with respect to 8,333 shares of common stock for each of the Company's non-employee directors. No other changes to the non-employee director compensation policy were approved and, on July 9, 2020, the Board approved the initial 8,333 2020 Director SAR award to each of the non-employee directors for an aggregate total of 58,333 2020 Directors SAR awards granted. The 2020 Director SAR awards vest on the first anniversary of grant subject to the director's continued service and will be settled in cash, have a per-share base amount of $8.40, and are in all cases subject to the terms and conditions of the Company's form of 2020 Director SAR award agreement.

Each SAR subject to a 2020 SAR award represents the right to a cash payment equal to the excess, if any, of (i) the fair market value of each underlying share of the Company's common stock, determined on the date of exercise of the SAR minus (ii) the base amount. Pursuant to the terms of the SAR awards, in no event may the cash payment for each SAR exceed $13.20, which is the maximum price per share of $21.60, minus the base amount of $8.40, subject to adjustment in accordance with the terms of the Stock Appreciation Right Award Agreement. The maximum price per share is the per-share value based on the Company's market capitalization at $250 million and the Company's outstanding shares of common stock, which was 11,611,829 shares on July 9, 2020.

On February 17, 2021, the compensation committee of the board of directors and the board approved a cash bonus program of cash-settled stock appreciation right ("2021 SAR") awards and cash-settled performance stock unit ("2021 PSU") awards to the Company's employees. An aggregate of 2021 SAR awards with respect to 100,000 shares of common stock and 2021 PSU awards with respect to 100,000 shares of common stock were granted to the Company's employees. The 2021 SAR awards will be settled in cash, vest 33% on the first anniversary of the date of grant, and the remaining 67% monthly over the next 24 months, have a per-share base amount of $22.65, which was the closing sales price of a share of the Company's common stock on the grant date, and are in all cases subject to the terms and conditions of the Company's form of SAR award agreement. Each SAR subject to a 2021 SAR award represents the right to a cash payment equal to the excess, if any, of (i) the fair market value of each underlying share of the Company's common stock, determined on the date of exercise of the 2021 SAR minus (ii) the base amount. Pursuant to the terms of the 2021 SAR awards, in no event may the cash payment for each SAR exceed $15.45, which is the maximum price per share of $38.10, minus the base amount of $22.65, subject to adjustment in accordance with the terms of the Stock Appreciation Right Award Agreement. The maximum price per share is the per-share value based on the Company's market capitalization at $600 million and the Company's outstanding shares of common stock, which was 15,767,492 shares on February 17, 2021. The 2021 SAR awards are cash-settled and were granted outside of the 2018 Plan and the 2021 Plan.

The 2021 PSU awards vest 20% upon the initiation of a new clinical program with an in-licensed compound, 20% for reaching the recommended Phase 2 dose for any compound, 20% for the first patient enrolled in the expansion cohort of the Phase 1 ON123300 clinical trial, 20% for the first patient enrolled in a registrational study for any compound, and 20% for the topline data of a registrational study for any compound. The 2021 PSU awards have a maximum value of $38.10 per share. The maximum price per share is the per-share value based on the Company's approximate market capitalization at $600 million and the Company's outstanding shares of common stock, which was 15,767,492 shares on February 17, 2021. In all cases, the 2021 PSU awards are subject to the terms and conditions of

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the Company's form of PSU award agreement. The 2021 PSU awards are cash-settled and were granted outside of the 2018 Plan and the 2021 Plan.

The fair value of the 2021 SARs granted has been estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	As of March 31, 2022
Risk-free interest rate	2.42 %
Expected volatility	132.18 %
Expected term	5.39 years
Expected dividend yield	0 %

During the three months ended March 31, 2022, the Company recognized $16,000 of reversals of compensation expense related to the SARs and PSUs. As of March 31, 2022, the SARs and PSUs liability was $70,000 and is included in accrued expenses. As of March 31, 2022, there was $6,000 of unrecognized compensation cost related to the 2020 SARs and PSUs and $168,000 of unrecognized compensation cost related to the 2021 SARs and PSUs.

9. 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 March 31, 2022 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.

10. Securities Registrations and Sales Agreements

January 2021 Offering

On January 7, 2021, the Company entered into a purchase agreement with certain institutional and accredited investors for the sale of an aggregate of 1,303,408 shares of the Company's common stock, at a purchase price of $6.675 per share.

Under the purchase agreement, subject to certain exceptions, the Company is prohibited from effecting or entering into an agreement to effect any "variable rate transactions" as defined in the purchase agreement for a period of five years following the closing of the offering.

In connection with the offering, pursuant to the purchase agreement we reimbursed Lincoln Park Capital Fund, LLC, as the lead investor ("Lincoln Park"), an aggregate of $100,000 for expenses incurred in connection with the offering, including any due diligence expenses and legal fees. Furthermore, pursuant to the purchase agreement, we have

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Notes to Condensed Consolidated Financial Statements (Continued)
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granted Lincoln Park certain rights to participate at fair value with other investors in up to 50% of the amount of any future offerings of common stock or securities exercisable for or convertible into common stock that the Company seeks to complete within one year after the closing of the offering, other than a firm commitment public offering.

The net proceeds to the Company from the offering, after deducting Lincoln Park's expenses and other estimated offering expenses payable by the Company were approximately $8.5 million.

The shares sold in the offering were offered and sold by the Company directly to the investors, without a placement agent, underwriter, broker or dealer, pursuant to an effective shelf registration statement on Form S-3 (File No. 333-237844) declared effective by the SEC on May 18, 2020, and the base prospectus contained therein. The offering closed on January 11, 2021.

February 2021 Offering

On February 10, 2021, the Company entered into an underwriting agreement with Guggenheim Securities, LLC, as representative of several underwriters, for the public offering of 1,666,667 shares of the Company's common stock, at a public offering price of $15.00 per share. Under the terms of the underwriting agreement, the Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 250,000 shares of common stock at the same price. The option was exercised prior to closing.

In connection with the offering, the Company paid the underwriters a cash fee equal to 6% of the gross proceeds in the offering and $100,000 in legal fees and expenses.

The net proceeds to the Company from the offering, including exercise of the underwriters' option, were approximately $26.7 million, after deducting fees and estimated offering expenses payable by the Company.

The offering was made pursuant to a registration statement (No. 333-237844) on Form S-3, which was initially filed by the Company with the SEC on April 24, 2020, amended on Form S-3/A that was filed with the SEC on May 15, 2020, and was declared effective by the SEC on May 18, 2020. The offering closed on February 16, 2021.

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 may 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 is the sales agent.

Under the Equity Distribution Agreement, the Company has 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 may sell 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 provides that Piper Sandler is 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 has no obligation to sell any shares under the Equity Distribution Agreement, and may at any time suspend solicitation and offers under the Equity Distribution Agreement. Through March 31, 2022, 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 three months ended March 31, 2022.

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The shares are issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-237844). 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.

September 2021 Offering

On September 23, 2021, the Company entered into an underwriting agreement with Guggenheim Securities, LLC, as representative of several underwriters, for the public offering of 5,000,000 shares of the Company's common stock, at a public offering price of $4.20 per share. Under the terms of the underwriting agreement, the Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 750,000 shares of common stock at the same price. The option was not exercised.

In connection with the offering, the Company paid the underwriters a cash fee equal to 6% of the gross proceeds in the offering and $100,000 in legal fees and expenses.

The net proceeds to the Company from the offering, including exercise of the underwriters' option, were approximately $19.5 million, after deducting fees and estimated offering expenses payable by the Company.

The offering was made pursuant to a registration statement (No. 333-237844) on Form S-3, which was initially filed by the Company with the SEC on April 24, 2020, amended on Form S-3/A that was filed with the SEC on May 15, 2020, and was declared effective by the SEC on May 18, 2020. The offering closed on September 28, 2021.

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, 2021 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 21, 2022. 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.

All common stock, equity, share and per share amounts have been retroactively adjusted to reflect a one-for-fifteen reverse stock split which was effective May 20, 2021.

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 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;
- the performance of third parties, including contract research organizations ("CROs") and third-party manufacturers; and
- the impact of the novel coronavirus disease, COVID-19, to global economy and capital markets, and to our business and our financial results.

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 solid tumors. We are currently evaluating potential compounds for in-licensing opportunities.

Our net losses were $4.1 million and $4.7 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $448.8 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 March 31, 2022, we had $50.8 million in cash and cash equivalents.

On January 12, 2021, we closed on an offering of common stock. We issued 1,303,408 shares of common stock and net proceeds were approximately $8.5 million. On February 16, 2021, we closed on an offering of common stock. We issued 1,916,667 shares of common stock and net proceeds were approximately $26.7 million. On September 28, 2021, we closed on an offering of common stock. We issued 5,000,000 shares of common stock and net proceeds were approximately $19.5 million.

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. Through March 31, 2022, 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.

On May 20, 2021, we amended our certificate of incorporation to effect a one-for-fifteen reverse stock split of our common stock. All common stock, equity, share and per share amounts in the financial statements and notes have been retroactively adjusted to reflect the reverse stock split.

On May 20, 2021, we amended our certificate of incorporation to decrease the number of authorized shares of common stock from 250,000,000 to 125,000,000.

We believe that our cash and cash equivalents of $50.8 million, at March 31, 2022, will be sufficient to fund our operations and ongoing trials for at least 18 months from the date of this filing. We do not have a recurring source of revenue to fund our operations and will need to raise additional funds to continue to develop and apply for regulatory approval for our drug candidates.

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 cyclin-dependent kinases (CDK) 2, 4, 6, and 9, 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 (IC_{50}) of narazaciclib palbociclib, ribociclib and

abemaciclib. IC_{50} 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 AMP-activated protein kinase (AMPK) catalytic subunit family and functions as a key regulator of cellular energy homeo-stasis (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. In addition, using a cellular based assay that measures kinase activity in intact cells, NanoBret technology, it was determined that narazaciclib inhibited CSF1R with an IC50 value of 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.

We and our partner, HanX Biopharmaceuticals, Inc. (“HanX”), have initiated phase 1 dose escalation clinical studies to begin evaluating the safety, tolerability and PK of narazaciclib in order to establish a recommended phase 2 dose (RP2D). Once we establish the RP2D, we intend to progress clinical development to determine whether the findings from preclinical studies may translate to clinical activity or potential clinical benefit in cancer patients.

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, a company focused on development of novel oncology products, for the further 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 (a “IND”) thereby enabling the studies necessary in order to seek IND approval by the National Medical Products Administration (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 study and study data outside of China.

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 US phase 1 study (Study 19-01) commenced in May 2021. Enrollment in the third dose cohort of the Phase 1 solid tumor study of narazaciclib is complete with no dose limiting toxicities (DLT’s) observed. The fourth dose cohort is currently ongoing. The study will assess the safety, tolerability and pharmacokinetics of narazaciclib administered orally at increasing doses starting at 40 mg daily for consecutive 28-day cycles in patients (n=36) with relapsed/refractory advanced cancer.

In partnership with HanX, a complementary Phase 1 dose escalation study (Study HX301) 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 is enrolling patients at 200 mg per day.

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 Retinoblastoma (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 AMP - activated protein kinase (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 stimulation 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.

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

We are currently supporting investigator-initiated studies (ISS) that are exploring the use of rigosertib for cancers driven by mutated Ras genes including a Phase 1/2a study of rigosertib in combination with a PD-1 inhibitor for patients with progressive 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) for future studies and characterize the safety profile of the combination treatment. Final results of the Phase 1 portion of the study are expected in late 2022. On June 28, 2021, we announced an update regarding this NSCLC study, with an expansion of the trial underway at the highest dose in the current protocol. To date, one patient with a dose limiting toxicity of hyponatremia has been observed. Continued dose escalation is being considered as we believe the maximum tolerated dose has not been reached. In addition, preliminary efficacy data support the preclinical observation of rigosertib augmenting the response to checkpoint inhibition (CPI) in patients who had previously failed all standard of care treatment, including CPI. Interim data presented at the 3rd Annual RAS Targeted Drug Development Summit (September 21-23, 2021), demonstrated two partial responses and one stable disease out of seven evaluable patients, or a clinical benefit rate of 43% (3/7). The three patients with clinical benefit harbored different KRAS mutations; suggesting that patients with a variety of KRAS mutations may have the potential to respond to the novel combination including rigosertib. We believe this supports further investigation of rigosertib in combination with CPI in KRAS mutated NSCLC.

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 CPI improved tumor growth inhibition and survival in a murine melanoma model that did not respond to 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 and we expect an ISS for continued development in the area will be open for enrollment in 1H2022.

Rigosertib as monotherapy

Based on rigosertib's activity against another important cell cycle pathway, PLK-1 (Antanasova, 2019), a Phase 1b/2 ISS with rigosertib monotherapy in patients with advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-SCC) is enrolling patients. As we disclosed in December 2021 early preliminary data from an investigator-initiated Phase 2 open label trial of rigosertib monotherapy in advanced squamous cell carcinoma complicating recessive dystrophic epidermolysis bullosa (RDEB- SCC) were presented at the Austrian Society of Dermatology and Venerology Annual Conference 2021, which took place from November 25 – 27, 2021.

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).

Data from the recent presentation are from a patient with a history of multiple, unresectable SCCs 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 remission of all lesions without signs of metastatic disease following 13 treatment cycles. The patient remains in complete remission and on drug, and the trial remains ongoing. An additional patient has recently been enrolled and additional patients are anticipated at sites in Salzburg, Austria; London, UK; and Philadelphia, Pennsylvania.

Though the trial's currently available safety and efficacy data are from only a single patient, the investigators believe they represent an 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.

Rare Disease Program in "RASopathies"

Based on the mechanism of action data published in the journal Cell in 2016, we initiated a collaborative development program focusing on a group of rare diseases with a well- defined molecular basis in expression or defects involving the Ras effector pathways. Since RASopathies are rare congenital diseases affecting young children, we embarked on a multifaceted collaborative program involving patient advocacy, government and academic organizations. RASopathies are usually caused by germline mutations in genes that alter the RAS subfamily and mitogen-activated protein kinases (MAPK) that control signal transduction and are among the most common genetic syndromes. Together, this group of diseases can impact more than 1 in 1,000 individuals, according to RASopathies.Net.

The NCI has conducted preclinical studies with cell lines from two pediatric solid tumors (rhabdomyosarcoma and neuroblastoma), including xenograft models. For both tumor cell lines, in vitro rigosertib exposure was associated with reduced cell viability associated with destabilization of microtubules, mitotic arrest and apoptosis. In a rhabdomyosarcoma xenograft model, rigosertib treatment delayed time to tumor progression and prolonged survival in the animals treated with rigosertib. (Kowalczyk, 2020)

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 21, 2022.

The full extent to which COVID-19 will directly or indirectly impact our business, results of operations and financial condition, including expenses and manufacturing, clinical trials and research and development costs, depends on future developments that are uncertain at this time.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31,		
	2022	2021	Change
Revenue	$ 56,000	$ 56,000	$ —
Operating expenses:			
General and administrative	2,186,000	2,217,000	31,000
Research and development	2,002,000	1,937,000	(65,000)
Total operating expenses	4,188,000	4,154,000	(34,000)
Loss from operations	(4,132,000)	(4,098,000)	(34,000)
Change in fair value of warrant liability	—	(636,000)	636,000
Other income, net	10,000	19,000	(9,000)
Net loss	$ (4,122,000)	$ (4,715,000)	$ 593,000

Revenues

Revenues for 2022 were consistent with 2021, and were due to the recognition of deferred revenue from our collaboration with SymBio.

General and administrative expenses

General and administrative expenses in total were similar for the three months ended March 31, 2022 compared to the three months ended March 31, 2021, decreasing by $31,000. This decrease was caused by $0.3 million decrease in investor relations, proxy solicitation, and fees related to our special meeting by proxy in 2021 which did not occur in 2022. This decrease was mostly offset by $0.2 million higher bonus accruals in the 2022 period and $0.1 million higher stock compensation expense in the 2022 period.

The details of our general and administrative expenses are:

	Three Months Ended March 31,	
	2022	2021
Professional & consulting fees	$ 462,000	$ 518,000
Stock based compensation	187,000	56,000
Personnel related	997,000	778,000
Public company costs	205,000	532,000
Insurance & other	335,000	333,000
	$ 2,186,000	$ 2,217,000

Research and development expenses

Research and development expenses increased by $0.1 million, or 3%, to $2.0 million for the three months ended March 31, 2022 from $1.9 million for the three months ended March 31, 2021. This increase was caused primarily by $0.6 million higher manufacturing costs related to narazaciclib drug substance and drug product manufacturing. This increase was partially offset by $0.4 million lower clinical development and consulting expenses on the INSPIRE program in the 2022 period, and also by $0.1 million lower personnel and stock compensation expense during the 2022 period, following cash-settled stock appreciation rights exercises from former employees in early 2021.

The details of our research and development expenses are:

	Three Months Ended March 31,	
	2022	2021
Preclinical & clinical development	$ 234,000	$ 567,000
Personnel related	585,000	821,000
Manufacturing, formulation & development	749,000	155,000
Stock based compensation	109,000	9,000
Consulting fees	325,000	385,000
	$ 2,002,000	$ 1,937,000

Change in fair value of warrant liability

The fair value of the warrant liability was reduced to $0 during the third quarter of 2021, following the expiration of the underlying tradable warrants. The change in the fair value of the warrant liability was $0.6 million during the three months ended March 31, 2021 based on the change in market value of the tradable warrants in the 2021 period.

Other income, net

Other income, net, was $10,000 and $19,000 for the three months ended March 31, 2022 and 2021, respectively. The change of $9,000 was due to lower foreign currency exchange gain, partially offset by higher interest income in the 2022 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 $4.1 million and $4.7 million for the three months ended March 31, 2022 and 2021, respectively. Our operating activities used $4.3 million and $6.6 million of net cash during the three months ended March 31, 2022 and 2021, respectively. At March 31, 2022, we had an accumulated deficit of $448.8 million, working capital of $45.4 million, and cash and cash equivalents of $50.8 million. We believe that our cash and cash equivalents as of March 31, 2022, will be sufficient to fund our operations and ongoing trials for at least 18 months from the date of this filing.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (4,296,000)	$ (6,648,000)
Investing activities	—	—
Financing activities	—	35,644,000
Effect of foreign currency translation	(7,000)	(16,000)
Net increase (decrease) in cash and cash equivalents	$ (4,303,000)	$ 28,980,000

Net cash used in operating activities

Net cash used in operating activities was $4.3 million for the three months ended March 31, 2022 and consisted primarily of a net loss of $4.1 million, including $0.3 million of noncash stock-based compensation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $0.5 million. Significant changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of $0.3 million, an increase in accounts payable of $0.4 million and decrease in accrued liabilities of $0.5 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.

Net cash used in operating activities was $6.6 million for the three months ended March 31, 2021 and consisted primarily of a net loss of $4.7 million, including an increase in the fair value of warrant liability of $0.6 million, and $0.1 million of noncash stock-based compensation. Changes in operating assets and liabilities resulted in a net increase in cash of $2.6 million. Significant changes in operating assets and liabilities included a decrease in accounts payable and accrued liabilities of $2.7 million due to timing of invoices and payments to our vendors, partially offset by an decrease 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 provided by financing activities

There were no cash flows from financing activities during the three months ended March 31, 2022. Net cash provided by financing activities was $35.6 million for the three months ended March 31, 2021 resulting from proceeds received from the sales of common stock and the exercise of warrants.

Material Cash Requirements

We believe that our cash and cash equivalents of $50.8 million at March 31, 2022, will be sufficient to fund our operations and ongoing trials for at least 18 months from the date of this filing. The consolidated financial statements 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 in existence.

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 2022 to be slightly higher than 2021. We expect clinical trial costs to increase as we focus on our earlier clinical stage compound, narazaciclib, and increased headcount in our clinical and regulatory groups. We would also expect an increase in costs for any completed potential in-licensing, the timing of which would 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.

For additional risks, please see “Risk Factors” in Part II of this report and in 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 March 31, 2022. 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 March 31, 2022, 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 March 31, 2022 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 information contained in this report, 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 21, 2022 which could materially affect our business, financial condition or future results. 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.

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 (formatted as Inline XBRL and contained in Exhibit 101)

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: May 13, 2022

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

Dated: May 13, 2022

/s/ MARK GUERIN
Mark Guerin
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: May 13, 2022

/s/ Steven M. Fruchtman, M.D.
Steven M. Fruchtman, M.D.
President and Chief Executive Officer
(*Principal Executive and Principal Operating 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: May 13, 2022

/s/ Mark Guerin
Mark Guerin
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 March 31, 2022, 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: May 13, 2022

/s/ Steven M. Fruchtman, M.D.
Steven M. Fruchtman, M.D.
President and Chief Executive Officer
(*Principal Executive and Principal Operating 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 March 31, 2022, 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: May 13, 2022

/s/ Mark Guerin
Mark Guerin
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.