

---

---

**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 September 30, 2023

Or

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

Commission file number: 001-36020

**Onconova Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**12 Penns Trail, Newtown, PA**

(Address of principal executive offices)

**22-3627252**

(I.R.S. Employer  
Identification No.)

**18940**

(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 November 1, 2023 was 21,003,409.

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 \$0.01 per share	ONTX	The Nasdaq Stock Market LLC

---

---

ONCONOVA THERAPEUTICS, INC.

TABLE OF CONTENTS FOR QUARTERLY REPORT ON FORM 10-Q  
FOR THE QUARTER ENDED SEPTEMBER 30, 2023

	<u>Page</u>
<u>PART I — FINANCIAL INFORMATION</u>	
<a href="#">Item 1. Financial Statements (Unaudited)</a>	3
<a href="#">Condensed Consolidated Balance Sheets</a>	3
<a href="#">Condensed Consolidated Statements of Operations</a>	4
<a href="#">Condensed Consolidated Statements of Comprehensive Loss</a>	5
<a href="#">Consolidated Statement of Stockholders' Equity (Deficit)</a>	6
<a href="#">Condensed Consolidated Statements of Cash Flows</a>	7
<a href="#">Notes to Condensed Consolidated Financial Statements</a>	8
<a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	16
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	29
<a href="#">Item 4. Controls and Procedures</a>	29
<u>PART II — OTHER INFORMATION</u>	
<a href="#">Item 1. Legal Proceedings</a>	30
<a href="#">Item 1A. Risk Factors</a>	30
<a href="#">Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Securities</a>	31
<a href="#">Item 3. Defaults Upon Senior Securities</a>	31
<a href="#">Item 4. Mine Safety Disclosures</a>	31
<a href="#">Item 5. Other Information</a>	31
<a href="#">Item 6. Exhibits</a>	31
<a href="#">SIGNATURES</a>	32

**PART I — FINANCIAL INFORMATION****Item 1. Financial Statements****Onconova Therapeutics, Inc.  
Condensed Consolidated Balance Sheets**

	September 30, 2023	December 31, 2022
<b>Assets</b>		
Current assets:	(unaudited)	
Cash and cash equivalents	\$ 25,244,000	\$ 38,757,000
Receivables	18,000	29,000
Prepaid expenses and other current assets	1,749,000	561,000
Total current assets	27,011,000	39,347,000
Property and equipment, net	26,000	24,000
Other non-current assets	1,000	1,000
Total assets	\$ 27,038,000	\$ 39,372,000
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 6,148,000	\$ 3,860,000
Accrued expenses and other current liabilities	3,300,000	3,960,000
Deferred revenue	226,000	226,000
Total current liabilities	9,674,000	8,046,000
Deferred revenue, non-current	2,847,000	3,017,000
Total liabilities	12,521,000	11,063,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value, 125,000,000 shares authorized, 21,003,409 and 20,925,992 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	210,000	209,000
Additional paid in capital	492,784,000	491,816,000
Accumulated deficit	(478,447,000)	(463,683,000)
Accumulated other comprehensive loss	(30,000)	(33,000)
Total stockholders' equity	14,517,000	28,309,000
Total liabilities and stockholders' equity	\$ 27,038,000	\$ 39,372,000

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Revenue	\$ 57,000	\$ 57,000	\$ 170,000	\$ 170,000
Operating expenses:				
General and administrative	2,686,000	2,105,000	7,010,000	6,430,000
Research and development	2,460,000	3,593,000	8,996,000	7,633,000
Total operating expenses	<u>5,146,000</u>	<u>5,698,000</u>	<u>16,006,000</u>	<u>14,063,000</u>
Loss from operations	(5,089,000)	(5,641,000)	(15,836,000)	(13,893,000)
Other income, net	350,000	243,000	1,072,000	349,000
Net loss	<u>\$ (4,739,000)</u>	<u>\$ (5,398,000)</u>	<u>\$ (14,764,000)</u>	<u>\$ (13,544,000)</u>
Net loss per share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.26)</u>	<u>\$ (0.70)</u>	<u>\$ (0.65)</u>
Basic and diluted weighted average shares outstanding	<u>21,002,937</u>	<u>20,915,408</u>	<u>20,981,097</u>	<u>20,902,251</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net loss	\$ (4,739,000)	\$ (5,398,000)	\$ (14,764,000)	\$ (13,544,000)
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustments, net	(2,000)	(20,000)	3,000	(47,000)
Other comprehensive income (loss), net of tax	(2,000)	(20,000)	3,000	(47,000)
Comprehensive loss	<u>\$ (4,741,000)</u>	<u>\$ (5,418,000)</u>	<u>\$ (14,761,000)</u>	<u>\$ (13,591,000)</u>

See accompanying notes to condensed consolidated financial statements.

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

	Three Month Periods Ended September 30, 2023 and 2022					
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount				
Balance at June 30, 2023	20,977,625	\$ 210,000	\$ 492,424,000	\$ (473,708,000)	\$ (28,000)	\$ 18,898,000
Net loss	—	—	—	(4,739,000)	—	(4,739,000)
Other comprehensive loss	—	—	—	—	(2,000)	(2,000)
Stock-based compensation	—	—	360,000	—	—	360,000
Shares issued for vested restricted stock units	25,784	—	—	—	—	—
Balance at September 30, 2023	<u>21,003,409</u>	<u>\$ 210,000</u>	<u>\$ 492,784,000</u>	<u>\$ (478,447,000)</u>	<u>\$ (30,000)</u>	<u>\$ 14,517,000</u>
Balance at June 30, 2022	20,895,563	\$ 209,000	\$ 491,181,000	\$ (452,865,000)	\$ (41,000)	\$ 38,484,000
Net loss	—	—	—	(5,398,000)	—	(5,398,000)
Other comprehensive loss	—	—	—	—	(20,000)	(20,000)
Stock-based compensation	—	—	305,000	—	—	305,000
Shares issued for vested restricted stock units	30,429	—	—	—	—	—
Balance at September 30, 2022	<u>20,925,992</u>	<u>\$ 209,000</u>	<u>\$ 491,486,000</u>	<u>\$ (458,263,000)</u>	<u>\$ (61,000)</u>	<u>\$ 33,371,000</u>

	Nine Month Periods Ended September 30, 2023 and 2022					
	Common Stock		Additional Paid in Capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total
	Shares	Amount				
Balance at December 31, 2022	20,925,992	\$ 209,000	\$ 491,816,000	\$ (463,683,000)	\$ (33,000)	\$ 28,309,000
Net loss	—	—	—	(14,764,000)	—	(14,764,000)
Other comprehensive income	—	—	—	—	3,000	3,000
Stock-based compensation	—	—	969,000	—	—	969,000
Shares issued for vested restricted stock units	77,417	1,000	(1,000)	—	—	—
Balance at September 30, 2023	<u>21,003,409</u>	<u>\$ 210,000</u>	<u>\$ 492,784,000</u>	<u>\$ (478,447,000)</u>	<u>\$ (30,000)</u>	<u>\$ 14,517,000</u>
Balance at December 31, 2021	20,895,563	\$ 209,000	\$ 490,644,000	\$ (444,719,000)	\$ (14,000)	\$ 46,120,000
Net loss	—	—	—	(13,544,000)	—	(13,544,000)
Other comprehensive loss	—	—	—	—	(47,000)	(47,000)
Stock-based compensation	—	—	842,000	—	—	842,000
Shares issued for vested restricted stock units	30,429	—	—	—	—	—
Balance at September 30, 2022	<u>20,925,992</u>	<u>\$ 209,000</u>	<u>\$ 491,486,000</u>	<u>\$ (458,263,000)</u>	<u>\$ (61,000)</u>	<u>\$ 33,371,000</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>
<b>Operating activities:</b>		
Net loss	\$ (14,764,000)	\$ (13,544,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	12,000	10,000
Stock compensation expense	969,000	842,000
Changes in assets and liabilities:		
Receivables	11,000	—
Prepaid expenses and other current assets	(1,188,000)	(778,000)
Other assets	—	9,000
Accounts payable	2,288,000	1,003,000
Accrued expenses and other current liabilities	(660,000)	218,000
Deferred revenue	(170,000)	(170,000)
Net cash used in operating activities	<u>(13,502,000)</u>	<u>(12,410,000)</u>
<b>Investing activities:</b>		
Payments for purchase of property and equipment	(14,000)	—
Net cash used in investing activities	<u>(14,000)</u>	<u>—</u>
Effect of foreign currency translation on cash	3,000	(47,000)
Net decrease in cash and cash equivalents	(13,513,000)	(12,457,000)
Cash and cash equivalents at beginning of period	38,757,000	55,070,000
Cash and cash equivalents at end of period	<u>\$ 25,244,000</u>	<u>\$ 42,613,000</u>

See accompanying notes to condensed consolidated financial statements.

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

**1. Nature of Business**

**The Company**

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

**Liquidity**

The Company has incurred recurring operating losses since inception. For the nine months ended September 30, 2023, the Company incurred a net loss of \$14,764,000 and as of September 30, 2023 the Company had generated an accumulated deficit of \$478,447,000. The Company anticipates that operating losses will 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 September 30, 2023, the Company had cash and cash equivalents of \$25,244,000. The Company believes that its cash and cash equivalents will be sufficient to fund its ongoing trials and business operations into the third quarter of 2024; therefore, based on current projections, the Company does not have sufficient cash and cash equivalents to support its operations for at least the 12 months following the date that these financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern through the one year period after the date that the financial statements are issued. Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, the Company may have based this estimate on assumptions that may prove to be wrong, and the Company's operating plan may change as a result of many factors currently unknown to the Company.

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

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

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

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

**Unaudited Interim Financial Information**

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

**Segment Information**

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

**Concentrations of Credit Risk and Off-Balance Sheet Risk**

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

At September 30, 2023 the Company had \$25,150,000 of its cash and cash equivalents in a Morgan Stanley Institutional Liquidity Fund. The fund is a AAA rated money market fund that invests in a portfolio of liquid, high-quality debt securities issued by the U.S. government. The fund resides in a custodial account held by U.S. Bank for which SVB Asset Management is the advisor.

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

**Significant Accounting Policies**

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

**Fair Value Measurements**

At both September 30, 2023 and December 31, 2022, the Company had no financial assets and liabilities measured at fair value on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

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

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

**Recent Accounting Pronouncements**

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

**3. Revenue**

The Company's revenue during the three and nine months ended September 30, 2023 and 2022 was from its license and collaboration agreement with Symbio.

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Symbio				
Upfront license fee recognition over time	\$ 57,000	\$ 57,000	\$ 170,000	\$ 170,000

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

Deferred revenue is as follows:

	Symbio Upfront Payment
Deferred balance at December 31, 2022	\$ 3,243,000
Recognition to revenue	(170,000)
Deferred balance at September 30, 2023	<u>\$ 3,073,000</u>

**4. Net Loss Per Share of Common Stock**

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

	September 30,	
	2023	2022
Warrants	337,684	491,586
Stock options	2,177,030	1,178,498
	<u>2,514,714</u>	<u>1,670,084</u>

**5. Warrants**

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

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

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2022	Warrants Issued	Warrants Exercised	Warrants Expired	Balance
								September 30, 2023
Non-tradable pre-funded warrants	Equity	\$ 2.25	July 2023	26	—	—	(26)	—
Non-tradable pre-funded warrants	Equity	\$ 2.25	none	3,522	—	—	—	3,522
Non-tradable pre-funded warrants	Equity	\$ 2.25	none	4,974	—	—	—	4,974
Non-tradable warrants	Equity	\$ 30.00	September 2023	7,306	—	—	(7,306)	—
Non-tradable warrants	Equity	\$ 3.00	November 2024	244,500	—	—	—	244,500
Non-tradable warrants	Equity	\$ 6.54375	December 2024	16,953	—	—	—	16,953
Non-tradable warrants	Equity	\$ 6.75450	December 2024	46,263	—	—	—	46,263
Non-tradable warrants	Equity	\$ 6.77850	December 2023	29,968	—	—	—	29,968
				<u>353,512</u>	<u>—</u>	<u>—</u>	<u>(7,332)</u>	<u>346,180</u>

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

**6. Balance Sheet Detail**

Prepaid expenses and other current assets:

	September 30, 2023	December 31, 2022
Research and development	\$ 1,098,000	\$ 233,000
Manufacturing	213,000	97,000
Insurance	135,000	191,000
Other	303,000	40,000
	<u>\$ 1,749,000</u>	<u>\$ 561,000</u>

Property and equipment:

	September 30, 2023	December 31, 2022
Property and equipment	\$ 84,000	\$ 70,000
Accumulated depreciation	(58,000)	(46,000)
	<u>\$ 26,000</u>	<u>\$ 24,000</u>

Accrued expenses and other current liabilities:

	September 30, 2023	December 31, 2022
Research and development	\$ 2,231,000	\$ 2,593,000
Employee compensation	854,000	1,187,000
Professional fees	215,000	180,000
	<u>\$ 3,300,000</u>	<u>\$ 3,960,000</u>

**7. Stock-Based Compensation**

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

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

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

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

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

The 2021 Plan was amended and restated following unanimous approval of the Company’s Board of Directors on May 23, 2022 and was approved by the Company’s shareholders on August 18, 2022. The amended 2021 Plan (the “Amended 2021 Plan”) allowed for an additional 2,000,000 shares of the Company’s common stock that may be issued with respect to awards made on and after August 18, 2022. At September 30, 2023, there were 916,352 shares available for future issuance.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General and administrative	\$ 200,000	\$ 119,000	\$ 534,000	\$ 377,000
Research and development	160,000	170,000	435,000	448,000
	<u>\$ 360,000</u>	<u>\$ 289,000</u>	<u>\$ 969,000</u>	<u>\$ 825,000</u>

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

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2022	1,397,763	\$ 7.15	9.18	\$ —
Granted	943,526	\$ 0.88	9.66	—
Exercised	—	\$ —	—	\$ —
Forfeitures/adjustments	(164,259)	\$ 13.08	—	—
Balance, September 30, 2023	<u>2,177,030</u>	<u>\$ 3.57</u>	<u>8.75</u>	<u>\$ 949.80</u>
Exercisable at September 30, 2023	<u>845,010</u>	<u>\$ 7.27</u>	<u>7.86</u>	<u>\$ —</u>

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 September 30, 2023, there was \$1,238,000 of unrecognized compensation expense related to the unvested stock options which is expected to be recognized over a weighted-average period of approximately 1.39 years.

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

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

	Nine months ended September 30.	
	2023	2022
Risk-free interest rate	3.89 %	2.45 %
Expected volatility	123.07 %	121.72 %
Expected term	5.68 years	5.70 years
Expected dividend yield	0 %	0 %
Weighted average grant date fair value	\$ 0.77	\$ 1.32

The weighted-average valuation assumptions were determined as follows:

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

On August 2, 2021, the compensation committee of the Board of Directors approved restricted stock unit grants to the Company’s employees (2021 RSU). An aggregate of 104,700 service-based RSUs were issued at a grant date fair value of \$5.19. The 2021 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. The 2021 RSU awards were granted under the 2021 Plan. During the nine months ended September 30, 2023, there was a vesting event for 25,784 of the 2021 RSUs. There were no expirations or cancellations of 2021 RSUs; there were forfeitures of 9,300 of the 2021 RSUs. On February 7, 2022, the compensation committee of the Board of Directors approved restricted stock unit grants to the Companies employees (2022 RSU). An aggregate of 148,343 service-based RSUs were issued at a grant date fair value of \$1.82. The 2022 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. During the nine months ended September 30, 2023, there was a vesting event for 43,567 of the 2022 RSUs. There were no expirations or cancellations of the 2022 RSUs during the period; there were forfeitures of 11,667 of the 2022 RSUs. On June 10, 2022, the compensation committee of the Board of Directors approved restricted stock unit grants to certain of the Company’s employees (2022 RSU2). An aggregate of 24,200 service-based RSUs were issued at a grant date fair value of \$1.33. The 2022 RSU2 awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. During the nine months ended September 30, 2023, there was a vesting event for 8,066 of the 2022 RSU2 awards. There were no expirations, forfeitures, or cancellations of the 2022 RSU2s. On March 13, 2023, the compensation committee of the Board of Directors approved restricted stock unit grants to the Companies employees (2023 RSU). An aggregate of 169,217 service-based RSUs were issued at a grant date fair value of \$0.73. The 2023 RSU awards will be settled in stock, vest 33% on each of the first and second anniversary of the date of grant, and vest 34% on the third anniversary of the date of grant. During the nine months ended September 30, 2023, there were no vesting events, expirations, or cancellations of the 2023 RSUs; there were forfeitures of 27,334 of the 2023 RSUs. At September 30, 2023, the unrecognized compensation cost related to unvested service-based RSUs was \$307,000, which will be recognized over the remaining service period of 1.49 years.

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

**Grants of PSUs and SARs**

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

**8. Research Agreements**

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

**9. Securities Registrations and Sales Agreements**

***August 2021 Equity Distribution Agreement***

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

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

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

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

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

### Cautionary Note Regarding Forward-Looking Statements

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

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

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

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

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

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

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

#### **Overview**

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

Our net losses were \$14.8 million and \$13.5 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of \$478.4 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 September 30, 2023, we had \$25.2 million in cash and cash equivalents. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and operations into the third quarter of 2024; therefore, based on current projections, we do not have sufficient cash and cash equivalents as of the date of this report to support our operations for at least the 12 months following the date that these financial statements are issued. Accordingly, substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these financial statements are issued.

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

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

#### ***Product Candidates / Compounds***

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

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

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

	<b>Narazaciclib</b>	<b>Palbociclib</b>	<b>Ribociclib</b>	<b>Abemaciclib</b>
Sponsor	Onconova	Pfizer	Novartis	Lilly
<b>CDK Family</b>				
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
<b>Other Kinases</b>				
CSF1R	0.7	>10,000	>10,000	>10,000
ARK 5/NUAK 1	5	1,400	1,540	773
FLT3	6.0	496	753	72

Source: *Reaction Biology 2021*

In addition to CDK 4/6, narazaciclib also inhibits ARK5 (NUAK1) with high potency with a 50% inhibitory concentration (IC50) of 4.95 nM (Report EPR-123300-001 and Reddy 2014) while palbociclib, ribociclib, and abemaciclib do not. The equilibrium dissociation constant (Kd) value of narazaciclib binding to ARK5 was found to be 19 nM, while a known NUAK1 specific inhibitor (HTH-015-01) was 790 nM. In addition, using a cellular based assay that measures kinase activity in intact cells, NanoBret technology, it was determined that narazaciclib inhibited ARK5 with an IC50 value of 30 nM, while 2 published inhibitors, HTH-015-01 and WZ4003, had IC50 values of >10,000 nM. ARK5 (also known as NUAK1) is a member of the AMPK catalytic subunit family and functions as a key regulator of cellular energy 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. The ability of narazaciclib to bind and inhibit CSF1R at low nanomolar values, in both in vitro and cell-based assays suggests that this compound may have an impact in cancers with a dependence on CSF1R signaling.

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

Narazaciclib's potent antitumor activity against mantle cell lymphoma (MCL) cell lines, independent of their sensitivity to the FDA-approved Bruton's tyrosine kinase inhibitor ibrutinib has been demonstrated in preclinical studies. Narazaciclib's activity against MCL cell lines was shown to be superior to that of the FDA-approved CDK 4/6 inhibitors palbociclib and ribociclib, and similar to that of the FDA-approved CDK 4/6 inhibitor abemaciclib. Combining narazaciclib with ibrutinib led to synergistic increases in antitumor activity against both ibrutinib-sensitive and ibrutinib-resistant MCL cell lines. Preclinical data from this study was presented at the 17th International Conference on Malignant Lymphoma, in Lugano, Switzerland, on June 14, 2023 and the European MCL Network Annual Meeting in Dublin, Ireland, on October 7, 2023.

In certain in vitro models, the kinase inhibitory profile of narazaciclib had high activity against CDK4, CDK6, ARK5, CSF1R, PDGFR $\beta$  and PI3K- $\delta$ , 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  $\mu$ M to 1.5  $\mu$ M. 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 (Seliciclib/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 protein phosphorylation. Abemaciclib is a multi-targeted kinase CDK4/6 inhibitor with low nano molar activity against CDK4/6. The second generation CDK4/6 inhibitors have substantially improved clinical outcomes for patients with hormonal-receptor (HR) positive metastatic breast cancer (Hortobagyi 2018, Sledge 2017, Finn 2016). Several CDK4/6 inhibitors (palbociclib, ribociclib and abemaciclib) have been approved and are now standard of care either alone (abemaciclib) or in combination with anti-estrogen therapy for patients with HR-positive, HER2-negative metastatic breast cancer. Another CDK4/6 inhibitor has recently been approved, trilaciclib, in the supportive care space, for the prevention of myelosuppression following chemotherapy.

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

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

Our IND submission to the US FDA was submitted in November 2020 and the FDA Study May Proceed letter was issued in December 2020. Enrollment into the complementary US phase 1 study (Study 19-01) with narazaciclib commenced in May 2021. In Study 19-01 in the US, narazaciclib is dosed on a continuous daily schedule. The study will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of narazaciclib administered orally at increasing doses starting at 40 mg daily for consecutive 28-day cycles in patients with relapsed/refractory advanced cancer. Enrollment in the sixth dose cohort (240 mg orally each day) of the Phase 1 solid tumor study of narazaciclib is complete with one dose limiting toxicity (DLT) observed. The seventh dose cohort (280 mg daily) is currently ongoing.

These studies are expected to provide preliminary safety data and the recommended Phase 2 dose and schedule for narazaciclib.

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

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

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

In addition to CDK4/6 and PI3 Kinase pathways, narazaciclib inhibits several other kinases in vitro including ARK5 (NUAK1) (IC<sub>50</sub> of 4.95 nM) (IBv.2 2022, Reddy, 2014) while palbociclib does not. ARK5 is a member of the AMPK family and is thought to function as a key regulator of cellular energy homeo-stasis (Liu, 2012) and is important in a number of cancer cell survival pathways. Overexpression of ARK5 is associated with poor prognosis in hepatocellular cancer (Cui, 2013), ovarian cancer (Phippen, 2016), colorectal cancer (Port, 2018) and glioblastoma (Lu, 2013). ARK5 is involved in the increased invasiveness, migration, and metastatic potential of breast cancer cells (Chang, 2012), colorectal cancer (Kusakai, 2004), gastric cancer (Chen, 2017), and multiple myeloma (Suzuki et al., 2005). Narazaciclib inhibits ARK5 which may result in down regulation of the mTOR/MYC/RB1 pathways leading to cell cycle arrest and apoptosis.

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

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

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

Overexpression of CSF-1 or CSF1R is associated with tumor aggressiveness and poor prognosis. Inhibiting the signaling pathway of CSF1R provides a method to reduce the number of M2 macrophages/TAMs within the tumor microenvironment and thus improve anti-tumor immunological therapy. Recent studies have found that CSF-1/CSF1R

axis blockade can improve the efficiency of immune checkpoint inhibitors, especially programmed death-ligand 1 inhibitors.

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

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

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

Based on data from continuous dosing studies in rats and monkeys, the safety profile of narazaciclib is anticipated to be better than the approved CDK4/6 inhibitors with myelosuppression and gastrointestinal toxicity being most common. Management of these adverse events is expected to follow that used for the approved CDK 4/6 inhibitors. We believe that the proposed mechanism of action of narazaciclib, the unmet medical need of the advanced cancers potentially targeted by narazaciclib and the anticipated safety profile of narazaciclib as seen in pre-clinical studies, support conducting clinical studies. To date in the ongoing Phase 1 clinical trials, there has been no significant myelosuppression or gastrointestinal toxicity.

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

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

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

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

Onconova initiated a multi-center Phase 1/2a trial evaluating its multi-kinase inhibitor, narazaciclib, in combination with letrozole as a second- or third-line therapy for recurrent metastatic LGGEC in 1Q23. Both narazaciclib and letrozole are administered orally in the ongoing Phase 1 dose escalation phase before moving to a Phase 2 expansion cohort designed to enroll approximately 30 patients. The first patient in this trial was dosed in May 2023 and the initial cohort (160mg) has completed the DLT observation period. No DLTs were observed.

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

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

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

#### *Rigosertib as monotherapy*

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

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

the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on June 3, 2023 and at the European Academy of Dermatology and Venereology (EADV) in Berlin, Germany, on October 12, 2023.

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

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

#### *Rare Disease Program in "RASopathies"*

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

#### **Critical Accounting Policies and Estimates**

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

**Results of Operations**

*Comparison of the Three Months Ended September 30, 2023 and 2022*

	Three Months Ended September 30,		Change
	2023	2022	
Revenue	\$ 57,000	\$ 57,000	\$ —
Operating expenses:			
General and administrative	2,686,000	2,105,000	(581,000)
Research and development	2,460,000	3,593,000	1,133,000
Total operating expenses	5,146,000	5,698,000	552,000
Loss from operations	(5,089,000)	(5,641,000)	552,000
Other income, net	350,000	243,000	107,000
Net loss	\$ (4,739,000)	\$ (5,398,000)	\$ 659,000

*Revenues*

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

*General and administrative expenses*

General and administrative expenses increased \$0.6 million, or 28%, to \$2.7 million for the three months ended September 30, 2023 from \$2.1 million for the three months ended September 30, 2022. This increase was caused by \$0.4 million in public company costs related to our annual general meeting and additional board members expenses, \$0.2 million increase in professional and consulting fees, and \$0.1 million increased stock based compensation expense, partially offset by \$0.1 million lower insurance expenses in the 2023 period.

The details of our general and administrative expenses are:

	Three Months Ended September 30,	
	2023	2022
Professional & consulting fees	\$ 539,000	\$ 363,000
Stock based compensation	200,000	119,000
Personnel related	729,000	673,000
Public company costs	983,000	586,000
Insurance & other	235,000	364,000
	<u>\$ 2,686,000</u>	<u>\$ 2,105,000</u>

*Research and development expenses*

Research and development expenses decreased by \$1.1 million, or 31%, to \$2.5 million for the three months ended September 30, 2023 from \$3.6 million for the three months ended September 30, 2022. This decrease was caused primarily by a \$0.8 million decrease in manufacturing costs related to the timing of narazaciclib drug substance and drug product manufacturing and a decrease of \$0.4 million in clinical development, offset by an increase of \$0.2 million in consulting expenses related to narazaciclib, and \$0.1 million lower personnel expenses due to lower headcount.

The details of our research and development expenses are:

	<b>Three Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Preclinical & clinical development	\$ 1,179,000	\$ 1,584,000
Personnel related	420,000	545,000
Manufacturing, formulation & development	265,000	1,054,000
Stock based compensation	160,000	170,000
Consulting fees	436,000	240,000
	<u>\$ 2,460,000</u>	<u>\$ 3,593,000</u>

*Other income, net*

Other income, net, was income of \$0.4 million and \$0.2 million for the three months ended September 30, 2023 and 2022, respectively. The change was due to \$0.2 million higher interest income in the 2023 period.

**Comparison of the Nine months ended September 30, 2023 and 2022**

	<b>Nine Months Ended September 30,</b>		<b>Change</b>
	<b>2023</b>	<b>2022</b>	
Revenue	\$ 170,000	\$ 170,000	\$ —
Operating expenses:			
General and administrative	7,010,000	6,430,000	(580,000)
Research and development	8,996,000	7,633,000	(1,363,000)
Total operating expenses	<u>16,006,000</u>	<u>14,063,000</u>	<u>(1,943,000)</u>
Loss from operations	(15,836,000)	(13,893,000)	(1,943,000)
Other income, net	1,072,000	349,000	723,000
Net loss	<u>\$ (14,764,000)</u>	<u>\$ (13,544,000)</u>	<u>\$ (1,220,000)</u>

*Revenues*

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

*General and administrative expenses*

General and administrative expenses were \$7.0 million for the nine months ended September 30, 2023 and \$6.4 million for the nine months ended September 30, 2022. Public company costs increased \$0.5 million related to our annual general meeting and additional board fees related to two new directors, professional and consulting fees increased \$0.3 million, and stock based compensation expense increased \$0.1 million in the 2023 period. These increases were partially offset by decreased by \$0.3 million lower insurance costs in the 2023 period.

The details of our general and administrative expenses are:

	<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Professional & consulting fees	\$ 1,534,000	\$ 1,255,000
Stock based compensation	534,000	377,000
Personnel related	2,506,000	2,591,000
Public company costs	1,670,000	1,149,000
Insurance & other	766,000	1,058,000
	<u>\$ 7,010,000</u>	<u>\$ 6,430,000</u>

### Research and development expenses

Research and development expenses increased by \$1.4 million, or 18%, to \$9.0 million for the nine months ended September 30, 2023 from \$7.6 million for the nine months ended September 30, 2022. This increase was caused primarily by a \$2.6 million increase in clinical development, preclinical development, and consulting expenses related primarily to the Phase 1 dose escalation and Phase 1/2 combination trial of narazaciclib. These increases were partially offset by \$1.0 million in lower manufacturing costs related to the timing of narazaciclib drug substance and drug product manufacturing, as well as lower personnel related expenses of \$0.2 million.

The details of our research and development expenses are:

	Nine Months Ended September 30,	
	2023	2022
Preclinical & clinical development	\$ 3,595,000	\$ 1,302,000
Personnel related	1,541,000	1,772,000
Manufacturing, formulation & development	2,147,000	3,168,000
Stock based compensation	435,000	448,000
Consulting fees	1,278,000	943,000
	<u>\$ 8,996,000</u>	<u>\$ 7,633,000</u>

### Other income, net

Other income, net, was income of \$1.1 million and \$0.3 million for the nine months ended September 30, 2023 and 2022, respectively. The change was due to \$0.8 million higher interest income in the 2023 period.

### Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of \$14.8 million and \$13.5 million for the nine months ended September 30, 2023 and 2022, respectively. Our operating activities used \$13.5 million and \$12.4 million of net cash during the nine months ended September 30, 2023 and 2022, respectively. At September 30, 2023, we had an accumulated deficit of \$478.4 million, working capital of \$17.3 million, and cash and cash equivalents of \$25.2 million. We believe that our cash and cash equivalents will be sufficient to fund our ongoing trials and business operations into the third quarter of 2024; therefore, based on current projections, we do not have sufficient cash and cash equivalents as of the date of this Form 10-Q filing to support our operations for at least the 12 months following the date that these financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern through the one-year period after the date that the financial statements are issued. Due to the inherent uncertainty involved in making estimates and the risks associated with the research, development, and commercialization of biotechnology products, we may have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us.

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

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments

relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

### Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	\$ (13,502,000)	\$ (12,410,000)
Investing activities	(14,000)	—
Financing activities	—	—
Effect of foreign currency translation	3,000	(47,000)
Net decrease in cash and cash equivalents	<u>\$ (13,513,000)</u>	<u>\$ (12,457,000)</u>

#### Net cash used in operating activities

Net cash used in operating activities was \$13.5 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of \$14.8 million, including \$1.0 million of noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net increase in cash of \$0.3 million. Significant changes in operating assets and liabilities included an increase in accounts payable of \$2.3 million and a decrease in accrued liabilities of \$0.7 million due to timing of invoices and payments to our vendors, an increase in prepaid expenses and other current assets of \$1.2 million, and a decrease in deferred revenue of \$0.2 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 \$12.4 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of \$13.5 million, including \$0.8 million of noncash stock-based compensation expense. Changes in operating assets and liabilities resulted in a net increase in cash of \$0.3 million. Significant changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of \$0.8 million, an increase in accounts payable of \$1.0 million and an increase in accrued liabilities of \$0.2 million due to timing of invoices and payments to our vendors, and a decrease in deferred revenue of \$0.2 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with Symbio.

### Material Cash Requirements

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

We are exploring various sources of funding for continued development of narazaciclib and any potential in-licensed compounds as well as our ongoing operations. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met. If we obtain regulatory approval for any of our product candidates, we expect to incur significant NDA preparation and

commercialization expenses. We do not currently have an organization for the sales, marketing, and distribution of pharmaceutical products. We may rely on licensing and co-promotion agreements with strategic or collaborative partners for the commercialization of our products in the United States and other territories. If we choose to build a commercial infrastructure to support marketing in the United States for any of our product candidates that achieve regulatory approval, such commercial infrastructure could be expected to include a targeted oncology sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to having any certainty about marketing approval. Furthermore, we have and expect to continue to incur additional costs associated with operating as a public company.

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

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

### **Item 4. Controls and Procedures**

#### **Managements’ Evaluation of our Disclosure Controls and Procedures**

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

#### **Changes in Internal Control Over Financial Reporting**

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

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

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

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

We are required to meet certain qualitative and financial tests to maintain the listing of our securities on the Nasdaq Capital Market (Nasdaq). As of November 14, 2023, we were not in compliance with the Nasdaq continued listing requirements related to minimum bid price.

On September 25, 2023, we received a letter from Nasdaq indicating that we failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2), which requires that companies listed on Nasdaq maintain a minimum closing bid price of at least \$1.00 per share.

Under Nasdaq Listing Rule 5810(c)(3)(A), we have a 180 calendar day grace period, or until March 25, 2024, to regain compliance by meeting the continued listing standard. The continued listing standard will be met if the Company's common stock has a minimum closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days during the 180-calendar day grace period.

If we are not in compliance by March 25, 2024, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intention to cure the minimum bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. At that time, we may appeal the Nasdaq staff's determination to a Nasdaq Hearings Panel.

We intend to monitor the closing bid price of the Company's common stock and consider our available options to resolve the noncompliance with the minimum bid price requirement.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

If we are unable to maintain compliance with the continued listing requirements of Nasdaq, our common stock could be delisted, making it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair our ability to raise capital.

**Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities**

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**

<b>Exhibit Number</b>	<b>Description</b>
10.1	* <a href="#">Employment Agreement by and between the Company and Victor Mandia Moyo, MBChB., dated as of October 2, 2023.</a>
31.1	* <a href="#">Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer</a>
31.2	* <a href="#">Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer</a>
32.1	** <a href="#">Section 1350 Certifications of Principal Executive Officer</a>
32.2	** <a href="#">Section 1350 Certifications of Principal Financial Officer</a>
101.INS	XBRL Instance – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File -The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

\* Filed herewith

\*\* Furnished herewith

**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: November 14, 2023

/s/ STEVEN M. FRUCHTMAN, M. D.

Steven M. Fruchtmán, M.D.  
President and Chief Executive Officer  
*(Principal Executive Officer)*

Dated: November 14, 2023

/s/ MARK GUERIN

Mark Guerin  
Chief Operating Officer and Chief Financial Officer  
*(Principal Financial Officer)*

## ONCONOVA THERAPEUTICS, INC.

## EMPLOYMENT AGREEMENT

This Employment Agreement (the “**Agreement**”) between Onconova Therapeutics, Inc., a Delaware corporation (the “**Company**”) and Victor Mandla Moyo, MBChB. (“**Employee**”) is effective as of the date of the Employee’s commencement of employment with the Company, which is expected to be no later than October 2, 2023 (the “**Effective Date**”).

WHEREAS, the Company desires to employ Employee and Employee desires to be so employed by the Company upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual promises and undertakings herein contained, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Duration of Agreement. This Agreement is effective on the date set forth above and has no specific expiration date. Unless terminated or amended in writing by the parties, this Agreement will govern Employee’s continued employment by the Company until that employment ceases in accordance with Section 4 hereof.

2. Duties.

(a) Position. Subject to all the terms and conditions hereof, the Company shall employ Employee, and Employee shall serve the Company as Chief Medical Officer. Employee shall report directly to the President and Chief Executive Officer of the Company.

(b) Best Efforts. As Employee’s position is a full-time position, Employee agrees to devote Employee’s full-time effort, attention, and energies, from such location to be mutually agreed upon between Employee and the President and Chief Executive Officer, to this position and to the promotion of the business and interests of the Company. Employee will not render any professional services or engage in any activity which might be competitive with, adverse to the best interest of, or create the appearance of a conflict of interest with the Company. Employee agrees to abide by the policies, rules and regulations of the Company as they may be amended from time to time. Employee may not engage in outside employment, consulting or board or committee service without first obtaining prior express permission of the Company’s Chief Executive Officer and Chief Financial Officer, acting together. The foregoing shall not be construed as preventing Employee from (i) serving on civic, educational, philanthropic or charitable boards or committees, or, with the prior written consent of the Company’s Chief Executive Officer and Chief Financial Officer, acting together in their sole discretion, on corporate boards, and (ii) managing personal investments, so long as such activities are permitted under the Company’s code of conduct and employment policies and do not violate the provisions of Sections 5, 6 or 7 of this Agreement. Notwithstanding the foregoing, Employee will be permitted to consult for Actuate Therapeutics for a period of three (3) months following the execution of this Agreement (the “**Actuate Period**”); provided that, during the Actuate Period, Employee shall prioritize and fully perform Employee’s employment duties under this Agreement (including compliance with Sections 5, 6, and 7 of this Agreement) and satisfy all of Employee’s obligations to the Company. For the avoidance of doubt, the Company does not consent to Employee engaging in consulting services for Actuate Therapeutics after the end of the Actuate Period, nor does the Company consent to Employee

---

engaging in outside employment or consulting under any other circumstances; except that Employee may continue to serve on the boards listed on Appendix A, which have been approved by the Chief Executive Officer and the Chief Financial Officer of the Company.

3. Compensation and Other Benefits.

(a) Salary. For all services rendered by Employee under this Agreement, the Company agrees to pay Employee at an initial annualized rate of four hundred fifty thousand, dollars (\$450,000), as may be adjusted from time to time (the "**Base Salary**"), in bi-weekly installments in accordance with the Company's normal payroll cycle, less customary and legally required withholdings.

(b) Annual Bonus. Employee shall be eligible to receive an annual bonus (the "**Bonus**") based on the performance of Employee and the Company. The determination of such performance and the amount of the Bonus, if any, shall be at the sole discretion of the Compensation Committee of the Board of Directors of the Company (the "**Committee**") but shall not exceed forty percent (40%) of Employee's Base Salary for the proportion of the year during which the Employee worked (the "**Target Bonus**"). In the event that Employee has earned a Bonus for a particular year, such Bonus shall be paid to Employee in the form of cash, stock options, shares of the Company's stock, or a combination thereof, at the Committee's discretion no later than sixty (60) days following the end of such year.

(c) Sign on Bonus as Forgivable Loan. On or before the second payroll cycle after the Effective Date, the Company agrees to pay Employee a sign on bonus of seventy-five thousand dollars (\$75,000) (the "**Sign on Bonus**"). The Sign on Bonus will be paid to Employee as a forgivable loan and treated as compensation on the date of payment. Employee agrees to pay back the Company the Sign On Bonus if Employee voluntarily resigns from his employment or is terminated for Cause, as defined below, on or before the twelve (12) month anniversary of the Effective Date. Employee agrees to execute related documentation such as a promissory note, if requested by the Company. Employee agrees that the Company may offset amounts owed to Company from Employee related to the Sign On Bonus against other payments owed to Employee if Employee voluntarily resigns from his employment or is terminated for Cause on or before the twelve (12) month anniversary of the Effective Date.

(d) Stock Option. Subject to the approval of the Committee, Employee will be granted a Nonqualified Stock Option (as defined in the Company 2021 Incentive Compensation Plan, as amended (the "**Plan**")) (the "**Option**"), pursuant to the terms of the Plan and/or a new plan or agreement under Nasdaq Listing Rule 5635(c)(4) and subject to the Company's standard form of Nonqualified Stock Option Award Agreement ("**Option Agreement**"). The number of shares of Company common stock subject to the Option is 125,000 shares. Vesting of the Option will be over four (4) years from the date of grant, with twenty-five percent (25%) vesting on the first anniversary of the date of grant and the remainder vesting in equal monthly installments for three (3) years thereafter, in each case subject to Employee's continued service with the Company through each applicable vesting dates. The exercise of the Option shall be subject to the provisions of the Option Agreement, the Plan, and/or the new plan or agreement under Nasdaq Listing Rule 5635(c)(4).

---

(e) Employee Benefits. During the term of this Agreement, Employee shall be entitled to participate in any employee benefit plans or programs of the Company that are made generally available from time to time by the Company to similarly situated employees, including, but not limited to, health insurance, a flexible spending account and 401(k) participation.

(f) Vacation and Holidays. The Employee shall be entitled each year to four (4) weeks of vacation, and to those holidays observed by the Company. Vacation shall be taken by the Employee at such time or times as are mutually convenient to the Employee and the Company.

(g) Reimbursement of Expenses. The Company shall reimburse the Employee for all reasonable expenses incurred by Employee in connection with Employee's employment hereunder, *provided, however*, that such expenses were incurred in conformance with the policies of the Company, as established from time to time, and that Employee submits detailed vouchers and other records reasonably required by the Company in support of the amount and nature of such expense.

(h) Taxes and Withholding. All compensation payable and other benefits provided under this Agreement shall be subject to customary and legally required withholding for income, F.I.C.A., and other employment taxes.

#### 4. Termination of Employment.

(a) Death of Employee. If Employee dies during the term of this Agreement, this Agreement shall terminate immediately and the Company shall pay to Employee's then-current spouse, if such spouse survives Employee, or if not, to Employee's estate, the balance of Employee's accrued and unpaid salary, unreimbursed expenses and unused accrued vacation time through the termination date.

(b) Disability of Employee. If Employee is unable to perform Employee's full-time regular duties by reason of incapacity, either physical or mental, for a period of twelve (12) consecutive weeks or ninety (90) days within any twelve (12)-month period, the Company shall have the right to terminate Employee's employment upon written notice to the Employee. If the Company decides to terminate Employee's employment under this Section 4(b), the Company shall pay to Employee only the balance of Employee's accrued and unpaid salary, unreimbursed expenses and unused, accrued vacation time through the termination date. If the Company decides not to terminate Employee's employment as allowed under this Section, the Company shall have the option of reducing the Base Salary thereafter payable to Employee by the amount of payment the Employee receives pursuant to any disability insurance policy or program sponsored by the Company.

(c) Termination for Cause. If Employee's employment is terminated by the Company for "Cause," as defined below, the Company shall pay Employee only the balance of Employee's accrued, but unpaid salary, unreimbursed expenses and unused, accrued vacation time through the termination date. The Company shall have the right to set off any amounts due to Employee by any amounts owed by Employee to the Company at the time Employee's employment terminates, and Employee hereby authorizes the Company to make this setoff. Employee's employment may be terminated for "Cause" at any time upon delivery of written notice to Employee. "**Cause**" means the occurrence of any of the following events: (i) any gross failure on the part of Employee (other

---

than by reason of disability as provided in Section 4(b)) to faithfully and professionally carry out Employee's duties or to comply with any other material provision of this Agreement, which failure continues after written notice thereof by the Company, *provided* that the Company shall not be required to provide such notice in the event that such failure (A) is not susceptible to remedy or (B) relates to the same type of acts or omissions as to which such notice has been given on a prior occasion; (ii) Employee's dishonesty (which shall include, without limitation, any misuse or misappropriation of the Company's assets), or other willful misconduct (including, without limitation, any conduct on the part of Employee intended to or likely to injure the business of the Company); (iii) Employee's conviction for any felony or for any other crime involving moral turpitude, whether or not relating to Employee's employment; (iv) in accordance with applicable federal, state or local laws, Employee's insobriety or use of illegal drugs, chemicals or controlled substances either (A) in the course of performing Employee's duties and responsibilities under this Agreement, or (B) otherwise affecting the ability of Employee to perform the same; (v) Employee's failure to comply with a lawful written direction of the Company; or (vi) any wanton and willful dereliction of duties by Employee. The existence of any of the foregoing events or conditions shall be determined by the Company in the exercise of its reasonable judgment.

(d) Termination by the Company without Cause or by Employee for Good Reason. If Employee's employment by the Company ceases due to a termination by the Company without Cause (as defined above) or a resignation by Employee for Good Reason (as defined below), in each case following the one (1)-year anniversary of the Effective Date, the Company shall:

(i) pay to Employee all accrued and unpaid Base Salary through the date of such cessation of employment at the time such Base Salary would otherwise be paid according to the Company's usual payroll practices;

(ii) to the extent then unpaid, pay to Employee the annual Bonus (if any) with respect to the fiscal year ended immediately prior to the cessation of Employee's employment, which such Bonus shall be paid at the time such Bonus would have otherwise been paid absent Employee's cessation of employment;

(iii) pay to Employee, subject to Employee's delivery to the Company of a waiver and release of claims agreement in a form acceptable to the Company (the "**Release**") that becomes effective and irrevocable in accordance with Section 17(d) (the "**Release Requirement**") and Employee's continued compliance with the restrictive covenants in Sections 5, 6 and 7 in this Agreement:

(A) in the event Employee's employment by the Company ceases due to a termination by the Company without Cause or by Employee for Good Reason other than during the Change in Control Protection Period (as defined below) (and, for the avoidance of doubt, following the one (1)-year anniversary of the Effective Date), monthly severance payments equal to one-twelfth (1/12) of the sum of (x) Employee's then current Base Salary, and (y) an amount equal to the Target Bonus for the fiscal year during which Employee's employment by the Company ceases, which severance payments shall be paid for the duration of the Severance Period (as defined below) in accordance with the Company's usual payroll practices, commencing within sixty (60) days following the date of termination and any payments that have not been made between the termination date and the date of the first payment will be paid with the first payment; or

---

(B) in the event Employee's employment by the Company ceases due to a termination by the Company without Cause or by Employee for Good Reason during the Change in Control Protection Period (and, for the avoidance of doubt, following the one-year anniversary of the Effective Date), a severance payment amount equal to the sum of (x) the Employee's then current Base Salary plus (y) an amount equal to the Target Bonus for the fiscal year during which Employee's employment by the Company ceases, in a lump sum payment less all applicable withholding taxes, within seventy-five (75) days following the date of his termination of employment;

(iv) subject to the Release Requirement and Employee's continued compliance with the restrictive covenants in Sections 5, 6 and 7 in this Agreement, cause any outstanding unvested options to purchase shares of stock of the Company previously awarded to Employee to become fully vested as of the date of his termination of employment pursuant to this Section 4(d); and

(v) subject to the Release Requirement and Employee's continued compliance with the restrictive covenants in Sections 5, 6 and 7 in this Agreement, if Employee validly elects to receive continuation coverage under the Company's group health plan pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), reimburse Employee for a portion of the applicable premium payable for such COBRA continuation coverage for the duration of the Severance Period in an amount equal to the employer's portion of such premiums at the rate in effect on Employee's termination date; *provided, however*, that if the Company determines that it cannot continue to provide Employee with such benefit (either pursuant to the terms of the applicable group health plan, as a result of applicable law, or otherwise), the Company shall make supplemental monthly severance payments to Employee in an amount equal to the monthly amount the Company would have otherwise reimbursed to Employee for his participation in such group health plan for the duration of the Severance Period.

For purposes of this Agreement:

"**Change in Control**" has the same meaning ascribed to it in the Plan.

"**Change in Control Protection Period**" shall mean the twelve (12)-month period following a Change in Control.

"**Good Reason**" shall mean: (i) the breach by the Company of any material provision of this Agreement (*provided, however*, that a reduction in Employee's Base Salary by less than twenty percent (20%) in and for any twelve (12) month period shall not be a material breach by the Company if it is made in connection with a reduction in base salaries imposed on a majority of other senior executives of the Company and Employee's Base Salary is not reduced by a percentage that is greater than the percentage by which the base salaries of a majority of other senior executives of the Company is reduced in and for that same twelve (12) month period); (ii) a relocation of Employee's principal business location to a location more than fifty (50) miles from Employee's then-current business location; or (iii) at any time there occurs any of the following which results in a material adverse change in Employee's duties, position, or compensation without the express prior written consent of Employee: (1) the sale or transfer, whether in one transaction or in a series of transactions, of substantially all of the assets of the Company; or (2) the merger or consolidation of the Company with or into any other person or entity under circumstances where the Company is not the surviving entity in such merger or where persons having control of the

---

Company immediately prior to the transaction are not in control of the Company immediately after the transaction. None of the foregoing events or conditions will constitute Good Reason unless Employee provides the Company with written objection to the event or condition within thirty (30) days following the occurrence thereof, the Company does not cure the event or condition within thirty (30) days of receiving that written objection, and Employee resigns Employee's employment within thirty (30) days following the expiration of that cure period.

"**Severance Period**" shall mean the nine (9)-month period immediately following the date Employee's employment with the Company ceases due to a termination by the Company without Cause or by Employee for Good Reason; *provided, however*, that in the event Employee's employment by the Company ceases due to a termination by the Company without Cause or by Employee for Good Reason during the Change in Control Protection Period, the Severance Period will equal twelve (12) months.

(e) Code Section 280G. It is the intention of Employee and of the Company that no payments by the Company to or for the benefit of Employee under this Agreement or any other agreement or plan, if any, pursuant to which Employee is entitled to receive payments or benefits shall be nondeductible to the Company by reason of the operation of Section 280G of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (the "**Code**") relating to parachute payments or any like statutory or regulatory provision. Accordingly, and notwithstanding any other provision of this Agreement or any such agreement or plan, if by reason of the operation of said Section 280G of the Code or any like statutory or regulatory provision, any such payments exceed the amount which can be deducted by the Company, such payments shall be reduced to the maximum amount which can be deducted by the Company. The Company shall make all reasonable efforts to avoid rendering such payments or benefits nondeductible. To the extent that payments exceeding such maximum deductible amount have been made to or for the benefit of Employee, such excess payments shall be refunded to the Company with interest thereon at the applicable Federal rate determined under Section 1274(d) of the Code, compounded annually, or at such other rate as may be required so that no such payments shall be nondeductible to the Company by reason of the operation of Section 280G of the Code or any like statutory or regulatory provision. To the extent any such reduction in payments is necessary, any amounts subject to Code Section 409A will be reduced first, then to the extent any remaining reduction is necessary such further reduction shall occur to the payments or benefits in the order that results in the greatest economic present value of all payments actually made to Employee.

(f) Voluntary Resignation. Employee may voluntarily resign from employment with the Company at any time. In the event Employee voluntarily resigns from employment with the Company, Employee shall provide the Company with thirty (30) days' notice of Employee's intent to resign. The Company shall pay Employee only the balance of Employee's accrued, but unpaid salary, unreimbursed expenses and any unused, accrued vacation time through Employee's last day of work.

(g) Deemed Resignation. Upon termination of Employee's employment for any reason, Employee shall be deemed to have resigned from all offices and board memberships, if any, then held with the Company or any of its affiliates, and, at the Company's request, Employee shall execute such documents as are necessary or desirable to effectuate such resignations.

---

(h) No Other Severance. Upon termination of Employee's employment for any reason, the Company will have no severance obligations under this Agreement other than as provided in this Section 4, which shall supersede any prior or contemporaneous oral or written severance plan, policy, program, or other arrangement maintained by the Company to the extent such benefits would provide for duplication of benefits to Employee.

5. Non-Competition.

(a) For purposes of this Agreement, "**Competitor**" shall mean any person, company, or entity whose primary business at the time is, or whose then-current business plan contemplates engaging in activities which may be, competitive with products and services that were or were being designed, conceived, marketed, sold, distributed and/or developed by the Company during Employee's employment by the Company or at the time of termination of Employee's employment by the Company.

(b) Employee agrees that so long as Employee is employed by the Company, and for a period of twelve (12) months after the termination of his employment, Employee will not, directly or indirectly, whether for compensation or not, own, manage, operate, join, control, work for, or participate in, or be connected as a stockholder, officer, employee, partner, creditor, guarantor, advisor or otherwise, with a Competitor. The foregoing shall not be construed, however, as preventing Employee from investing his assets in such form or manner as will not require services on the part of Employee in the operations of the businesses in which such investments are made, *provided* that any such business is publicly owned and the interest of Employee therein is solely that of an investor owning not more than five percent (5%) of the outstanding equity securities of any such business. Should Employee breach the provisions of this Paragraph, the Company shall, in addition to any equitable or legal relief to which it is otherwise entitled, be entitled to cease all payments and benefits under the terms of this Agreement and shall be entitled to pursue all remedies it might have including, but not limited to, those contained in this Agreement.

(c) For the period of twelve (12) months after the termination of this Agreement for any reason whatsoever, Employee shall not hire, retain or engage as a director, officer, employee, agent or in any other capacity any person or persons who are employed by the Company or who were at any time (within a period of six (6) months immediately prior to the date of Employee's termination) employed by the Company or otherwise interfere with the relationship between such persons and the Company.

(d) If the period of time or area herein specified should be adjudged unreasonable in any court proceeding, then the period of time shall be reduced by such number of months or the area shall be reduced by elimination of such portion thereof as deemed unreasonable, so that this covenant may be enforced during such period of time and in such area as is adjudged to be reasonable.

6. Confidential Information.

(a) At all times during Employee's employment and thereafter, Employee will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Company's Proprietary Information (defined below), except as such use may be required in connection with Employee's work for the Company, or unless an officer of the Company expressly authorizes such

---

disclosure in writing. Employee will obtain Company's written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that relates to Employee's work for Company and/or incorporates any Proprietary Information. Employee hereby assigns to the Company any rights Employee may have or acquire in such Proprietary Information and recognizes that all Proprietary Information shall be the sole property of the Company and its assigns.

(b) The term "**Proprietary Information**" shall mean any and all confidential and/or proprietary knowledge, data or information of the Company, whether acquired by Employee while employed by the Company, during Employee's prior service as a consultant to the Company, or otherwise. By way of illustration but not limitation, "Proprietary Information" includes but is not limited to (i) trade secrets, inventions, mask works, ideas, methods, processes, formulas, chemical structures and methods for chemical synthesis, structure-activity relationships, assay methodologies, characteristics, equipment and equipment designs, results, formulations and biological, pharmacological, toxicological and clinical data, physical, chemical or biological materials, source and object codes, data, programs, other works of authorship, know-how, improvements, discoveries, developments, compilations, shop practices, supplier lists, designs and techniques (hereinafter collectively referred to as "**Inventions**"); and (ii) information regarding plans for research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers; and (iii) information regarding the skills and compensation of other employees of the Company. Notwithstanding the foregoing, it is understood that, at all times, Employee is free to use information which is generally known in the trade or industry, which is not gained as a result of a breach of this Agreement, and which is acquired as a result of Employee's own skill, knowledge, know-how and experience.

(c) Employee understands, in addition, that the Company has received and in the future will receive from third parties confidential or proprietary information ("**Third Party Information**") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the period of Employee's employment and thereafter, Employee will hold Third Party Information in the strictest confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for the Company) or use, except in connection with Employee's work for the Company, Third Party Information unless expressly authorized by an officer of the Company in writing.

(d) During Employee's employment by the Company, Employee will not improperly use or disclose any confidential information or trade secrets, if any, of any of his former employers or any other person to whom Employee has an obligation of confidentiality, and Employee will not bring onto the premises of the Company any unpublished documents or any property belonging to any former employer or any other person to whom Employee has an obligation of confidentiality, unless such action is consented to in writing by all persons to whom the relevant obligation of confidentiality is owed. Employee shall not work on Company projects on the grounds of, or using the equipment of, any third party, unless such work is agreed to by the Company in writing.

(e) Upon termination of his employment, Employee shall return to the Company all Proprietary Information in any tangible form in Employee's possession, including copies thereof.

---

7. Company Right to Inventions.

(a) Inventions, if any, patented or unpatented, which Employee made prior to the commencement of Employee's employment with the Company are excluded from the scope of this Agreement. To preclude any possible uncertainty, Employee has provided on Appendix B (Previous Inventions) attached hereto a complete list of all Inventions that Employee has, alone or jointly with others, conceived, developed or reduced to practice or caused to be conceived, developed or reduced to practice prior to the commencement of Employee's employment with the Company, that Employee considers to be Employee's property or the property of third parties, and that Employee wishes to have excluded from the scope of this Agreement (collectively referred to as "**Prior Inventions**"). If disclosure of any such Prior Invention would cause Employee to violate any prior confidentiality agreement, Employee understands that Employee shall not list such Prior Inventions in Appendix B but shall only disclose a cursory name for each such invention (bearing in mind that where necessary the naming shall not be so specific as to violate the confidentiality obligation), a listing of the party(ies) to whom the invention belongs, and the fact that full disclosure as to such invention has not been made for that reason. Space is provided on Appendix B for this purpose. If, in the course of Employee's employment with the Company, Employee incorporates a Prior Invention into a Company product, process or machine, the Company is hereby granted and shall have, to the extent of Employee's right to make such grant, a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use, import, sell and offer to sell such Prior Invention. Notwithstanding the foregoing, Employee agrees that Employee will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions without the Company's prior written consent.

(b) Subject to Section 7(d), Employee hereby assigns and agrees to assign in the future (when any such Inventions are first reduced to practice or a description thereof first fixed in a tangible medium, as applicable) to the Company all of Employee's right, title and interest in and to any and all Inventions, whether or not patentable or registerable under patent, intellectual property, copyright or similar statutes, made or conceived or reduced to practice or learned by Employee, either alone or jointly with others, during the period of Employee's employment with the Company. Inventions assigned to the Company, or to a third party as directed by the Company pursuant to this Section 7(b), are hereinafter referred to as "**Company Inventions.**"

(c) During the period of Employee's employment, Employee will promptly disclose to the Company fully and in writing all Inventions authored, conceived or reduced to practice by Employee, either alone or jointly with others. In addition, Employee will promptly disclose to the Company all patent applications filed by Employee or on Employee's behalf during Employee's employment and within one (1) year after termination of employment. At the time of each such disclosure, Employee will advise the Company in writing of any Inventions that Employee believes qualify for exclusion from Employee's obligation to assign hereunder; and Employee will at that time provide to the Company in writing all evidence necessary to substantiate that belief.

(d) As directed by the Company, Employee agrees to assign all Employee's right, title and interest in and to any particular Company Invention to a third party, including without limitation the United States.

---

(e) Employee acknowledges that all original works of authorship which are made by Employee (solely or jointly with others) within the scope of Employee's employment and which are protectable by copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C. § 101).

(f) Employee will assist the Company in every proper way to obtain, and from time to time enforce, United States and foreign trade secret, patent, copyright, mask work and other intellectual property rights ("**Proprietary Rights**") relating to Company Inventions in any and all countries. To that end, Employee will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, Employee will execute, verify and deliver assignments of such Proprietary Rights to the Company, its successor in interest, or its designee. Employee's obligation to assist the Company with respect to Proprietary Rights relating to such Company Inventions in any and all countries shall continue beyond the termination of Employee's employment.

In the event the Company is unable for any reason, after reasonable effort, to secure Employee's signature on any document needed in connection with the actions specified in this Section 7(f), Employee hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Employee's agent and attorney-in-fact, which appointment is coupled with an interest, to act for and on Employee's behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by Employee.

(g) Employee agrees to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that may be required by the Company) of all Proprietary Information developed by Employee and all Inventions made by Employee during the period of Employee's employment at the Company, which records shall be available to and remain the sole property of the Company at all times.

(h) Employee represents that Employee's performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence information acquired by Employee in confidence or in trust prior to Employee's employment by the Company. Employee has not entered into, and Employee agrees that Employee will not enter into, any agreement either written or oral in conflict herewith.

8. Remedies. Because Employee's services are personal and unique and because Employee may have access to and become acquainted with the Proprietary Information of the Company, the Company shall have the right to enforce this Agreement and any of its provisions by injunction, or other equitable relief, without bond (if allowed by applicable law), and without prejudice to any other rights and remedies that the Company may have for a breach of this Agreement. In the event that Employee performs services for other entities while employed by the Company or leaves the employ of the Company, Employee hereby consents to the notification of Employee's new employer of Employee's rights and obligations under this Agreement.

9. Arbitration. Any and all disputes between the parties (except actions to enforce the provisions of Sections 5, 6 or 7 of this Agreement), arising under or relating to this Agreement or

---

any other dispute arising between the parties, including claims arising under any employment discrimination laws, shall be adjudicated and resolved exclusively through binding arbitration before the American Arbitration Association pursuant to the American Arbitration Association's then-in-effect National Rules for the Resolution of Employment Disputes (hereafter "**Rules**"), available at <https://www.adr.org/sites/default/files/National%20Rules%20for%20the%20Resolution%20of%20Employment%20Disputes%20Jan%2001%2C%202004.p> as of the date hereof. The initiation and conduct of any arbitration hereunder shall be in accordance with the Rules and each side shall bear its own costs and counsel fees in such arbitration. Any arbitration hereunder shall be conducted in Philadelphia, Pennsylvania, and any arbitration award shall be final and binding on the Parties. The arbitrator shall have no authority to depart from, modify, or add to the written terms of this Agreement. The arbitration provisions of this Section 9 shall be interpreted according to, and governed by, the Federal Arbitration Act, 9 U.S.C. § 1 *et seq.*, and any action pursuant to such Act to enforce any rights hereunder shall be brought exclusively in the United States District Court for the Eastern District of Pennsylvania. The parties consent to the jurisdiction of (and the laying of venue in) such court.

10. **General Indemnification.** The Company shall indemnify the Employee against any and all demands, claims, damages and suits, actions and legal proceedings brought against the Employee, in his individual capacity or in his official capacity, as agent and/or Employee of the Company for claims arising during his employment. In addition, the Company shall advance to the Employee reasonable attorney's fees in connection with the foregoing.

11. **Severability.** The terms of this Agreement and each Paragraph thereof shall be considered severable and the invalidity or unenforceability of any part thereof shall not affect the validity or enforceability of the remaining portions or provisions hereof.

12. **Notices.** Any notice required or permitted to be given under this Agreement shall be sufficient, if in writing and delivered by registered or certified mail or overnight delivery service to his residence in the case of Employee, or to its principal office in the case of the Company.

13. **Assignment.** The rights and obligations of the Company under this Agreement shall inure to the benefit of and be binding upon its successors and assigns. Neither this Agreement nor any rights or interests herein or created hereby may be assigned or otherwise transferred voluntarily or involuntarily by Employee.

14. **Waiver.** The waiver by the Company or Employee of a breach of any provision of this Agreement by the other shall not operate or be construed as a waiver of any subsequent breach.

15. **Applicable Law.** This Agreement shall be interpreted and construed under the laws of the Commonwealth of Pennsylvania.

16. **Entire Agreement; Prior Agreements.** This instrument contains the entire agreement of the parties with respect to the subject matter hereof and supersedes any and all prior or contemporaneous agreements, oral or written, concerning the subject matter contained herein, including without limitation any prior agreements between the Company and Employee. It may not be changed or altered, except by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification, extension or discharge is sought.

---

17. Code Section 409A.

(a) Notwithstanding anything herein to the contrary, this Agreement is intended to be interpreted and applied so that the payments and benefits set forth herein shall either be exempt from the requirements of Code Section 409A or shall comply with the requirements of Code Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be exempt from or in compliance with Code Section 409A. The parties hereto agree that the payments and benefits set forth herein comply with or are exempt from the requirements of Code Section 409A and agree not to take any position, and to cause their affiliates, successors and assigns not to take any position, inconsistent with such interpretation for any reporting purposes, whether internal or external.

(b) Notwithstanding anything in this Agreement or elsewhere to the contrary, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits that constitute "non-qualified deferred compensation" within the meaning of Code Section 409A upon or following a termination of the Employee's employment unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service" and the date of such separation from service shall be treated as the date of termination for purposes of any such payment or benefits. Notwithstanding any other provision of this Agreement to the contrary, if the Employee is a "specified employee" within the meaning of Code Section 409A and the regulations issued thereunder, and a payment or benefit provided for in this Agreement would be subject to additional tax under Code Section 409A if such payment or benefit is paid within six (6) months after the Employee's "separation from service" (within the meaning of Code Section 409A), then such payment or benefit required under this Agreement shall not be paid (or commence) during the six-month period immediately following the Employee's separation from service except as provided in the immediately following sentence. In such an event, any payments or benefits that would otherwise have been made or provided during such six (6)-month period and which would have incurred such additional tax under Code Section 409A shall instead be paid to the Employee in a lump-sum cash payment on the earlier of (i) the first regular payroll date of the seventh (7<sup>th</sup>) month following the Employee's separation from service or (ii) the tenth (10<sup>th</sup>) business day following the Employee's death.

(c) It is intended that each installment of any severance payments and benefits provided under this Agreement shall be treated as a separate "payment" for purposes of Code Section 409A. Neither the Employee nor the Company shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Code Section 409A. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Code Section 409A to the extent that such reimbursements or in-kind benefits are subject to Code Section 409A, including, where applicable, the requirements that (i) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (ii) the reimbursement of an eligible expense shall be made promptly and in all cases on or before the last day of the calendar year following the year in which the expense is incurred and (iii) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

---

(d) Notwithstanding anything contained herein to the contrary in this Agreement, to the extent that any payments due under this Agreement as a result of Employee's termination of employment are subject to Employee's execution and delivery of the Release, (i) if Employee fails to execute the Release on or prior to the Release Expiration Date (as defined below) or timely revokes Employee's acceptance of the Release thereafter, Employee shall not be entitled to any payments or benefits otherwise conditioned on the Release, and (ii) in any case where Employee's date of termination and the last day the Release may be considered or, if applicable, revoked, fall in two separate taxable years, any payments required to be made to Employee that are conditioned on the Release and are treated as nonqualified deferred compensation for purposes of Code Section 409A shall be made in the later taxable year. For purposes of this Section 17(d), "**Release Expiration Date**" shall mean (x) if Employee is under 40 years old as of the date of termination, the date that is seven (7) days following the date upon which the Company timely delivers the Release to Employee, and (y) if Employee is 40 years or older as of the date of termination, the date that is twenty-one (21) days following the date upon which the Company timely delivers the Release to Employee, or, in the event that Employee's termination of employment is "in connection with an exit incentive or other employment termination program" (as such phrase is defined in the Age Discrimination in Employment Act of 1967), the date that is forty-five (45) days following such delivery date. To the extent that any payments of nonqualified deferred compensation (within the meaning of Code Section 409A) due under this Agreement as a result of Employee's termination of employment are delayed pursuant to this Section 17(d), such amounts shall be paid in a lump sum on the first payroll date following the date that Employee executes and does not revoke the Release (and the applicable revocation period has expired) or, in the case of any payments subject to Section 17(d)(ii), on the first payroll period to occur in the subsequent taxable year, if later.

18. Whistleblower Protections and Trade Secrets. Notwithstanding anything to the contrary contained herein, nothing in this Agreement prohibits Employee from reporting possible violations of federal law or regulation to any United States governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies). Furthermore, in accordance with 18 U.S.C. § 1833, notwithstanding anything to the contrary in this Agreement: (i) Employee shall not be in breach of this Agreement, and shall not be held criminally or civilly liable under any federal or state trade secret law (x) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (y) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (ii) if Employee files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Employee may disclose the trade secret to Employee's attorney, and may use the trade secret information in the court proceeding, if Employee files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order.

19. Clawback Policy. Employee acknowledges and agrees that to the extent permitted under applicable law, all amounts payable under this Agreement are subject to the terms of any applicable Clawback Policy and, to the extent permitted by applicable law, including without limitation Section 409A of the Code (as defined below), all amounts payable under this Agreement are

---

subject to offset in the event that Employee has an outstanding clawback, recoupment or forfeiture obligation to the Company under the terms of any applicable Clawback Policy. In the event of a clawback, recoupment or forfeiture event under an applicable Clawback Policy, the amount required to be clawed back, recouped or forfeited pursuant to such policy shall be deemed not to have been earned under the terms of this Agreement or otherwise, and the Company shall be entitled to recover from Employee the amount specified under the policy to be clawed back, recouped or forfeited. For the purposes of this Agreement, "**Clawback Policy**" means any clawback, recoupment or forfeiture provisions of any applicable clawback, recoupment or forfeiture policy (including, without limitation, a clawback policy required to be implemented by an applicable stock exchange) approved by the Board of Directors of the Company (or a committee thereof), as in effect from time to time, whether approved before or after the effective date of this Agreement. Employee acknowledges and agrees that Employee will be bound by the terms of any such Clawback Policy as if it were set forth in this Agreement.

20. Counterparts. This Amendment may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original and all of which shall constitute the same instrument. Any and all counterparts may be executed by facsimile.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

**ONCONOVA THERAPEUTICS, INC.**

By: \_\_\_\_\_  
Steven M. Fruchtman, M.D.  
President and CEO

**EMPLOYEE:**

By: \_\_\_\_\_  
Victor Mandla Moyo, MBChB.

---

**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: November 14, 2023

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

---

**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: November 14, 2023

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

---

**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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven Fruchtman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2023

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

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

---

**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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Guerin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2023

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

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

---