UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

Or

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

Commission file number: 001-36020

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

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

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

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

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

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

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

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

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

The number of outstanding shares of the registrant's Common Stock, par value $0.01 per share, as of May 1, 2021 was 236,714,031.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.01 per share	ONTX	The Nasdaq Stock Market LLC
Common Stock Warrants	ONTXW	The Nasdaq Stock Market LLC

ONCONOVA THERAPEUTICS, INC.

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FOR THE QUARTER ENDED MARCH 31, 2021

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Onconova Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 48,005,000	$ 19,025,000
Receivables	38,000	37,000
Prepaid expenses and other current assets	607,000	722,000
Total current assets	48,650,000	19,784,000
Property and equipment, net	49,000	52,000
Other non-current assets	150,000	150,000
Total assets	$ 48,849,000	$ 19,986,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,988,000	$ 4,833,000
Accrued expenses and other current liabilities	3,112,000	4,962,000
Deferred revenue	226,000	226,000
Total current liabilities	7,326,000	10,021,000
Warrant liability	957,000	321,000
Deferred revenue, non-current	3,413,000	3,469,000
Total liabilities	11,696,000	13,811,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000,000 authorized at March 31, 2021 and December 31, 2020, none issued and outstanding at March 31, 2021 and December 31, 2020		
Common stock, $0.01 par value, 250,000,000 authorized at March 31, 2021 and December 31, 2020, 236,687,391 and 185,943,267 shares issued and outstanding at March 31, 2021 and December 31, 2020	2,367,000	1,859,000
Additional paid in capital	468,059,000	432,858,000
Accumulated other comprehensive (loss) income	(2,000)	14,000
Accumulated deficit	(433,271,000)	(428,556,000)
Total stockholders' equity	37,153,000	6,175,000
Total liabilities and stockholders' equity	$ 48,849,000	$ 19,986,000

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue	$ 56,000	$ 52,000
Operating expenses:		
General and administrative	2,217,000	1,807,000
Research and development	1,937,000	3,370,000
Total operating expenses	4,154,000	5,177,000
Loss from operations	(4,098,000)	(5,125,000)
Change in fair value of warrant liability	(636,000)	(63,000)
Other income, net	19,000	96,000
Net loss	$ (4,715,000)	$ (5,092,000)
Net loss per share, basic and diluted	$ (0.02)	$ (0.03)
Basic and diluted weighted average shares outstanding	219,242,077	160,346,087

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2021	**2020**
Net loss	$ (4,715,000)	$ (5,092,000)
Other comprehensive loss, before tax:		
Foreign currency translation adjustments, net	(16,000)	(6,000)
Other comprehensive loss, net of tax	(16,000)	(6,000)
Comprehensive loss	$ (4,731,000)	$ (5,098,000)

See accompanying notes to condensed consolidated financial statements.

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

	Three Month Periods Ended March 31, 2021 and 2020					
	Common Stock		Additional Paid in	Accumulated	Accumulated other comprehensive	
	Shares	Amount	Capital	deficit	(loss) income	Total
Balance at December 31, 2020	185,943,267	$ 1,859,000	$ 432,858,000	$ (428,556,000)	$ 14,000	$ 6,175,000
Net loss	-	-	-	(4,715,000)	-	(4,715,000)
Other comprehensive loss	-	-	-	-	(16,000)	(16,000)
Exercise of stock options	43,000	1,000	16,000	-	-	17,000
Stock-based compensation	-	-	65,000	-	-	65,000
Issuance of common stock, net	48,301,124	483,000	34,664,000	-	-	35,147,000
Issuance of common stock upon exercise of warrants	2,400,000	24,000	456,000	-	-	480,000
Balance at March 31, 2021	236,687,391	$ 2,367,000	$ 468,059,000	$ (433,271,000)	$ (2,000)	$ 37,153,000
Balance at December 31, 2019	111,167,352	$ 1,112,000	$ 413,879,000	$ (403,399,000)	$ (18,000)	$ 11,574,000
Net loss	-	-	-	(5,092,000)	-	(5,092,000)
Other comprehensive loss	-	-	-	-	(6,000)	(6,000)
Stock-based compensation	-	-	93,000	-	-	93,000
Issuance of common stock upon exercise of warrants	28,586,200	286,000	5,431,000	-	-	5,717,000
Issuance of common stock, net	27,662,518	276,000	8,786,000	-	-	9,062,000
Balance at March 31, 2020	167,416,070	$ 1,674,000	$ 428,189,000	$ (408,491,000)	$ (24,000)	$ 21,348,000

See accompanying notes to condensed consolidated financial statements.

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

	Three Months ended March 31,	
	2021	**2020**
Operating activities:		
Net loss	$ (4,715,000)	$ (5,092,000)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,000	3,000
Change in fair value of warrant liabilities	636,000	63,000
Stock compensation expense	65,000	93,000
Changes in assets and liabilities:		
Receivables	(1,000)	53,000
Prepaid expenses and other current assets	115,000	(145,000)
Accounts payable	(845,000)	(88,000)
Accrued expenses and other current liabilities	(1,850,000)	(1,294,000)
Deferred revenue	(56,000)	(56,000)
Net cash used in operating activities	(6,648,000)	(6,463,000)
Financing activities:		
Proceeds from the sale of common stock and warrants, net of costs	35,147,000	9,062,000
Proceeds from the exercise of warrants	480,000	5,717,000
Proceeds from the exercise of stock options	17,000	-
Net cash provided by financing activities	35,644,000	14,779,000
Effect of foreign currency translation on cash	(16,000)	(6,000)
Net increase in cash and cash equivalents	28,980,000	8,310,000
Cash and cash equivalents at beginning of period	19,025,000	22,726,000
Cash and cash equivalents at end of period	$ 48,005,000	$ 31,036,000

See accompanying notes to condensed consolidated financial statements.

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

1. Nature of Business

The Company

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

The Company has entered into several license and collaboration agreements. In 2011, the Company entered into a license agreement, as subsequently amended, with SymBio Pharmaceuticals Limited ("SymBio"), which grants SymBio certain rights to commercialize rigosertib in Japan and Korea. In December 2017, the Company entered into a license and collaboration agreement with HanX Biopharmaceuticals, Inc. ("HanX") for the further development, registration and commercialization of ON 123300 in greater China. ON 123300 is a preclinical compound which the Company believes has the potential to overcome the limitations of current generation CDK 4/6 inhibitors. Under the terms of the agreement, the Company received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX provides all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval, which was received in January 2020. The Company and HanX also intended for these studies to comply with the FDA standards for IND approval. Accordingly, such studies were used by the Company for an IND filing with the US FDA in November 2020. The FDA Study May Proceed letter was issued in December 2020. The Company maintains global rights outside of China. On March 2, 2018, the Company entered into a License, Development and Commercialization Agreement (the "Pint License Agreement") with Pint International SA (which, together with its affiliate Pint Pharma GmbH, are collectively referred to as "Pint"). Under the terms of the agreement, the Company granted Pint an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and commercialize any pharmaceutical product containing rigosertib in all uses of rigosertib in certain Latin American countries. In May 2019, the Company entered into a License and Collaboration Agreement (the "HanX License Agreement") with HanX. Under the terms of the HanX License Agreement, the Company granted HanX an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and commercialize any pharmaceutical product (the "HanX Product") containing rigosertib in all uses of rigosertib or the HanX Product in human therapeutic uses in the People's Republic of China, Hong Kong, Macau and Taiwan (the "HanX Territory"). In connection with the HanX License Agreement, the Company also entered into a Securities Purchase Agreement with each of HanX and Abundant New Investments Ltd. ("Abundant"), an affiliate of HanX (each, a "Securities Purchase Agreement" and together, the "Securities Purchase Agreements"). HanX did not fulfill its obligations under the HanX License Agreement and in January 2020, in accordance with the terms of the HanX License Agreement, the HanX License Agreement was deemed to be void ab initio. Upon this termination, the rights to HanX Product in the HanX Territory reverted to the Company in accordance with the terms of the HanX License Agreement. In addition, the Securities Purchase Agreements terminated automatically effective upon the termination of the HanX License Agreement in accordance with the Securities Purchase Agreements. In November 2019, the Company entered into a Distribution, License and Supply Agreement (the "Knight License Agreement") with Knight Therapeutics Inc. ("Knight"). Under the terms of the Knight License Agreement, the Company granted Knight (i) a non-exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and manufacture any product (the "Knight Licensed Product") containing rigosertib for Canada (and Israel, should Knight exercise its option as set forth in the Knight License Agreement) (the "Knight Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know-how, to commercialize the Knight Licensed Product in the Knight Territory and in the Field. Knight has also agreed to obtain from the Company all of its requirements of the Knight Licensed Products for the Knight Territory, and the Company has agreed to supply Knight with all of its requirements of the Knight Licensed Products. In December 2019, the Company entered into a Distribution, License and Supply Agreement (the "STA License Agreement") with Specialised Therapeutics Asia Pte. Ltd. ("STA"). Under the terms of the STA License Agreement, the Company granted STA (i) a non-exclusive, royalty -bearing license, with the right to sublicense, under certain Company patent rights and know-how, to develop and manufacture any product (the "STA Licensed Product") containing rigosertib for Australia and New Zealand (the "STA Territory") and in human uses (the "Field"), and (ii) an exclusive, royalty-bearing license, with the right to sublicense, under certain Company patent rights and know- how, to commercialize the STA Licensed Product in the STA Territory and in the Field. STA has also agreed to obtain from the Company all of its requirements of the STA Licensed Products for the STA Territory, and the Company has agreed to supply STA with all of its requirements of the STA Licensed Products.

Liquidity

The Company has incurred recurring operating losses since inception. For the three months ended March 31, 2021, the Company incurred a net loss of $4,715,000 and as of March 31, 2021 the Company had generated an accumulated deficit of $433,271,000. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of its product candidates and its preclinical programs, strategic alliances and its administrative organization. At March 31, 2021, the Company had cash and cash equivalents of $48,005,000. The Company will require substantial additional financing to fund its ongoing clinical trials and operations, and to continue to execute its strategy.

On January 3, 2020, the Company closed on an offering of common stock. The Company issued 27,662,518 shares of common stock and net proceeds were approximately $9.0 million. In addition, during the year ended December 31, 2020; 45,863,397 warrants were exercised, resulting in proceeds of $10.3 million.

On January 11, 2021, the Company closed on an offering of common stock. The Company issued 19,551,124 shares of common stock and net proceeds were approximately $8.5 million. On February 16, 2021, the Company closed on an offering of common stock. The Company issued 28,750,000 shares of common stock and net proceeds were approximately $26.7 million. In addition, during the quarter ended March 31, 2021; 2,400,000 warrants were exercised, resulting in proceeds of $0.5 million.

Following the unsuccessful conclusion of the INSPIRE trial, the Company has taken steps to reduce its cash expenditures. From September 2020 to December 2020, the Company implemented a workforce reduction of employees in research and development who were primarily focused on preparing the NDA for the use of rigosertib in higher risk MDS. In total, 10 employees were terminated, representing approximately 43% of the Company's workforce. A severance related charge of approximately $1,207,000, which includes a non-cash charge of approximately $29,000 related to the accelerated vesting of outstanding stock options, was recorded in the year ended December 31, 2020. The accrued severance balance remaining at March 31, 2021 was $586,000 and is included in accrued expenses and other liabilities on the balance sheet. It will be paid in periodic amounts through September 2021. On October 30, 2020, the Company notified its landlord of its intention to not renew its office space lease. The lease expired in February 2021 and was modified to a month-to-month lease for a portion of the space. The Company is evaluating less expensive space alternatives, including having some or all employees work remotely.

The Company has and may continue to delay, scale-back, or eliminate certain of its research and development activities and other aspects of its operations until such time as the Company is successful in securing additional funding. The Company is exploring various dilutive and non-dilutive sources of funding, including equity financings, strategic alliances, business development and other sources. The future success of the Company is dependent upon its ability to obtain additional funding. There can be no assurance, however, that the Company will be successful in obtaining such funding in sufficient amounts, on terms acceptable to the Company, or at all. The Company believes that its cash and cash equivalents will be sufficient to fund its ongoing trials and business operations for more than eighteen months from the date of this filing.

COVID-19

While the Company is not aware of a material impact from the novel coronavirus disease ("COVID-19") pandemic through March 31, 2021, the full extent to which COVID-19 will directly or indirectly impact the Company's business, results of operations and financial condition, including manufacturing, clinical trials and research and development costs, depends on future developments that are highly uncertain at this time.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2021, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2021 and 2020, the consolidated statements of stockholders' equity for the three months ended March 31, 2021 and 2020 and the condensed consolidated statements of cash flows for the three months ended March 31, 2021 and 2020 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2021, the results of its operations for the three months ended March 31, 2021 and 2020, and its cash flows for the three months ended March 31, 2021 and 2020. The financial data and other information disclosed in these notes related to the three months ended March 31, 2021 and 2020 are unaudited. The results for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, 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, 2020 included in the Company's annual report on Form 10-K filed with the SEC on March 18, 2021.

Segment Information

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

2. Summary of Significant Accounting Policies (Continued)

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2020 included in the Company's annual report on Form 10-K filed with the SEC on March 18, 2021. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

Fair Value Measurements

The carrying amounts reported in the accompanying consolidated financial statements for cash and cash equivalents, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. The fair value of the warrant liability is discussed in Note 7, "Fair Value Measurements."

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606). The Company applies ASC 606 to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of ASC 606, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company derives revenue from collaboration and licensing agreements and from the sale of products associated with material transfer, collaboration and supply agreements.

License, Collaboration and Other Revenues

The Company enters into licensing and collaboration agreements, under which it licenses certain of its product candidates' rights to third parties. The Company recognizes revenue related to these agreements in accordance with ASC 606. The terms of these arrangements typically include payment from third parties of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of the licensed product.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligation under each of its agreements, the Company performs the five steps described above. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement of personnel costs, discount rates and probabilities of technical and regulatory success.

2. Summary of Significant Accounting Policies (Continued)

Licensing of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front-fees. The Company evaluates the measure of progress each reporting period, and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal will not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensees, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in their period of adjustment.

Manufacturing supply services. Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assesses if these options provide material rights to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded when the customer obtains control of the goods, which is upon shipment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some of all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from its license agreements.

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements

In June 2016, the FASB issued new guidance on the accounting for credit losses on financial instruments. The guidance was amended in November 2019. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The guidance is effective for the Company in fiscal years beginning after December 15, 2022, and interim periods within those years, with early adoption permitted. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements.

3. Revenue

The Company's revenue during the three ended March 31, 2021 and 2020 was from its license and collaboration agreement with SymBio.

	Three Months Ended March 31,	
	2021	2020
Symbio		
Upfront license fee recognition over time	$ 56,000	$ 56,000
Supplies and other	-	(4,000)
	$ 56,000	$ 52,000

Deferred revenue is as follows:

	Symbio Upfront Payment
Deferred balance at December 31, 2020	$ 3,695,000
Recognition to revenue	56,000
Deferred balance at March 31, 2021	$ 3,639,000

4. Net Loss Per Share of Common Stock

The following potentially dilutive securities outstanding at March 31, 2021 and 2020 have been excluded from the computation of diluted weighted average shares outstanding, as they would be antidilutive (reflects the number of common shares as if the dilutive securities had been converted to common stock):

	March 31,	
	2021	**2020**
Warrants	7,683,037	27,373,567
Stock options	645,392	1,017,393
	8,328,429	28,390,960

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. Some of the Company's warrants are classified as liabilities because in certain circumstances they could require cash settlement.

Warrants outstanding and warrant activity (reflects the number of common shares as if the warrants were converted to common stock) for the three months ended March 31, 2021 is as follows:

Description	Classification	Exercise Price	Expiration Date	Balance December 31, 2020	Warrants Issued	Warrants Exercised	Warrants Expired	Balance March 31, 2021
Non-tradable warrants	Liability	$ 172.50	July 2021	6,456	-	-	-	6,456
Tradable warrants	Liability	$ 73.80	July 2021	212,801	-	-	-	212,801
Non-tradable pre-funded warrants	Equity	$ 0.15	July 2023	394	-	-	-	394
Non-tradable warrants	Equity	$ 1.60	December 2022	392,834	-	-	-	392,834
Non-tradable warrants	Equity	$ 14.10	March 2021	5,000	-	-	(5,000)	-
Non-tradable warrants	Equity	$ 21.15	March 2021	8,333	-	-	(8,333)	-
Non-tradable warrants	Equity	$ 7.7895	June 2021	15,000	-	-	-	15,000
Non-tradable pre-funded warrants	Equity	$ 0.15	none	52,834	-	-	-	52,834
Non-tradable warrants	Equity	$ 1.600	December 2022	1,806,104	-	-	-	1,806,104
Non-tradable pre-funded warrants	Equity	$ 0.15	none	74,617	-	-	-	74,617
Non-tradable warrants	Equity	$ 2.00	September 2023	109,585	-	-	-	109,585
Non-tradable warrants	Equity	$ 0.20	November 2024	6,142,500	-	(2,400,000)	-	3,742,500
Non-tradable warrants	Equity	$ 0.43625	December 2024	254,298	-	-	-	254,298
Non-tradable warrants	Equity	$ 0.45030	December 2024	693,943	-	-	-	693,943
Non-tradable warrants	Equity	$ 0.45190	December 2023	449,516	-	-	-	449,516
				10,224,215	-	(2,400,000)	(13,333)	7,810,882

The tradable warrants which expire in July 2021 were issued in connection with a financing transaction completed in August 2016. Subsequent to the closing of that financing transaction, the Company executed a one-for-fifteen reverse stock split in September 2018. As a result, each of the 3,192,140 warrants is exercisable for one-fifteenth of one share of common stock at an exercise price of $4.92 per warrant. The table above shows the number of shares of common stock which could be obtained by the exercise of all of the outstanding warrants, 212,801; and shows the exercise price for fifteen of the warrants, $73.80.

6. Balance Sheet Detail

Prepaid expenses and other current assets:

	March 31, 2021	December 31, 2020
Research and development	$ 47,000	$ 189,000
Manufacturing	99,000	90,000
Insurance	248,000	263,000
Other	213,000	180,000
	$ 607,000	$ 722,000

Property and equipment:

	March 31, 2021	December 31, 2020
Property and equipment	$ 70,000	$ 70,000
Accumulated depreciation	(21,000)	(18,000)
	$ 49,000	$ 52,000

Accrued expenses and other current liabilities:

	March 31, 2021	December 31, 2020
Research and development	$ 1,903,000	$ 2,541,000
Employee compensation	1,093,000	2,239,000
Professional fees	116,000	182,000
	$ 3,112,000	$ 4,962,000

7. Fair Value Measurements

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.

On January 5, 2016, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an institutional investor providing for the issuance and sale by the Company of 12,912 shares of Common Stock, at a purchase price of $142.50 per share and warrants to purchase up to 6,456 shares of Common Stock (the "Warrants") for aggregate gross proceeds of $1,840,000. The Company has classified the warrants as a liability (see Note 5). The estimated fair value using the Black-Scholes pricing model was approximately $0 at March 31, 2021 and December 31, 2020.

On July 29, 2016 the Company closed on a Rights Offering, issuing 239,986 shares of Common Stock, 212,801 Tradable Warrants and 43,760 Pre-Funded Warrants. The Tradable Warrants are exercisable for a period of five years for one share of Common Stock at an exercise price of $73.80 per share. After the one-year anniversary of issuance, the Company may redeem the Tradable Warrants for $0.001 per Tradable Warrant if the volume weighted average price of its Common Stock is above $184.50 for each of 10 consecutive trading days. The Company has classified the Tradable Warrants as a liability (see Note 5). The Tradable Warrants have been listed on the Nasdaq Capital Market since issuance and the Company regularly monitors the trading activity. The Company has determined that an active and orderly market for the Tradable Warrants has developed and that the Nasdaq Capital Market price is the best indicator of fair value of the warrant liability. The quoted market price was used to determine the fair value at December 31, 2020 and March 31, 2021.

The Company estimated the fair value of the non-tradable warrant liability at March 31, 2021, using the Black-Scholes option pricing model with the following weighted-average assumptions:

Risk-free interest rate	0.06%
Expected volatility	123.95%
Expected term	0.83 years
Expected dividend yield	0%

Expected volatility is based on the historical volatility of the Company's Common Stock since its IPO in July 2013.

7. Fair Value Measurements (Continued)

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2021 and December 31, 2020:

	Fair Value Measurement as of:							
	March 31, 2021				December 31, 2020			
	Level 1	Level 2	Level 3	Balance	Level 1	Level 2	Level 3	Balance
Tradable warrants liability	$ 957,000	$ -	$ -	$ 957,000	$ 321,000	$ -	$ -	$ 321,000
Non-tradable warrants liability	-	-	-	-	-	-	-	-
Total	$ 957,000	$ -	$ -	$ 957,000	$ 321,000	$ -	$ -	$ 321,000

There were no transfers between levels in any of the periods reported.

8. Stock-Based Compensation

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

Under the 2018 Plan, the Company may grant incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards to employees, non-employee directors and consultants, and advisors. The maximum aggregate number of shares of the Company's common stock that may be issued under the 2018 Plan is 402,354.

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 589,500 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. At March 31, 2021, there were 365,792 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 as follows for the three months ended March 31, 2021 and 2020:

	Three months ended March 31,	
	2021	**2020**
General and administrative	$ 56,000	$ 45,000
Research and development	9,000	48,000
	$ 65,000	$ 93,000

8. Stock-Based Compensation (Continued)

A summary of stock option activity for the three months ended March 31, 2021 is as follows:

		Options Outstanding			
	Shares Available for Grant	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance, December 31, 2020	185,089	869,095	$ 24.58	8.38	$ —
Authorized	—	—			
Granted	(15,000)	15,000	$ 0.845	9.85	
Exercised	—	(43,000)	$ 0.31	8.96	$ 6,699
Forfeitures	195,703	(195,703)	$ 66.30	7.35	
Balance, March 31, 2021	365,792	645,392	$ 12.99	8.37	$ —
Vested or expected to vest, March 31, 2021		633,564	$ 12.99	8.37	$ —
Exercisable at March 31, 2021		359,688	$ 22.79	8.08	$ —

Information with respect to stock options outstanding and exercisable at March 31, 2021 is as follows:

Exercise Price	Shares	Exercisable
$0.30 - $0.85	472,140	203,546
$3.39 – $3.41	25,332	25,332
$4.34 – $7.05	126,207	109,097
$22.50 – $97.50	16,332	16,332
$222.00 - $223.50	594	594
$348.00 – $597.00	1,264	1,264
$651.00 – $1,129.50	1,637	1,637
$1,992.00 - $2,268.00	1,551	1,551
$4,156.50 - $4,371.00	335	335
	645,392	359,688

The Company accounts for all stock-based payments made to 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. In accordance with authoritative guidance, the fair value of non-employee stock-based awards is re-measured as the awards vest, and the resulting increase in fair value, if any, is recognized as expense in the period the related services are rendered.

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, including estimating the fair value of the Company's Common Stock, assumptions related to the expected price volatility of the Common Stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

As of March 31, 2021, there was $157,000 of unrecognized compensation expense related to the unvested stock options which is expected to be recognized over a weighted-average period of approximately 1.61 years.

8. Stock-Based Compensation (Continued)

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

	Three months ended March 31,	
	2021	**2020**
Risk-free interest rate	0.62%	0.45%
Expected volatility	124.67%	105.14%
Expected term	6.25 years	6.00 years
Expected dividend yield	0%	0%
Weighted average grant date fair value	$ 0.24	$ 0.25

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 since its IPO in July 2013.

- 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%.

- Estimated forfeiture rate: The Company's estimated annual forfeiture rate on stock option grants was 4.14% in 2021 and 2020, based on the historical forfeiture experience.

Grants of PSUs and SARs

On July 9, 2020, the compensation committee of the board of directors and the board approved a cash bonus program of cash-settled stock appreciation right ("2020 SAR") awards and cash-settled performance stock unit ("2020 PSU") awards to the Company's employees. An aggregate of 2020 SAR awards with respect to 3,850,700 shares of common stock and 2020 PSU awards with respect to 1,863,300 shares of common stock were granted to the Company's employees. The 2020 SAR awards will be settled in cash, vest 33% on the first anniversary of the date of grant, and the remaining 67% monthly over the next 24 months, have a per-share base amount of $0.56, which was the closing sales price of a share of the Company's common stock on the grant date, and are in all cases subject to the terms and conditions of the Company's form of SAR award agreement.

The 2020 PSU awards vest 50% upon the submission of a new drug application ("NDA") to the U.S. FDA for rigosertib in higher-risk myelodysplastic syndromes ("HR-MDS") and 50% upon U.S. FDA approval of rigosertib for HR-MDS. The 2020 PSU awards have a maximum value of $1.44 per share. The maximum price per share is the per-share value based on the Company's market capitalization at $250 million and the Company's outstanding shares of common stock, which was 174,177,448 shares on July 9, 2020. In all cases, the 2020 PSU awards are subject to the terms and conditions of the Company's form of PSU award agreement.

8. Stock-Based Compensation (Continued)

In addition, on July 9, 2020, based on the recommendation of the compensation committee, the board approved a change in the non-employee director compensation policy that would provide for an annual SAR award ("2020 Director SAR") with respect to 125,000 shares of common stock for each of the Company's non-employee directors. No other changes to the non-employee director compensation policy were approved and, on July 9, 2020, the Board approved the initial 125,000 2020 Director SAR award to each of the non-employee directors for an aggregate total of 875,000 2020 Directors SAR awards granted. The 2020 Director SAR awards vest on the first anniversary of grant subject to the director's continued service and will be settled in cash, have a per-share base amount of $0.56, and are in all cases subject to the terms and conditions of the Company's form of 2020 Director SAR award agreement.

Each SAR subject to a 2020 SAR award represents the right to a cash payment equal to the excess, if any, of (i) the fair market value of each underlying share of the Company's common stock, determined on the date of exercise of the SAR minus (ii) the base amount. Pursuant to the terms of the SAR awards, in no event may the cash payment for each SAR exceed $0.88, which is the maximum price per share of $1.44, minus the base amount of $0.56, subject to adjustment in accordance with the terms of the Stock Appreciation Right Award Agreement. The maximum price per share is the per-share value based on the Company's market capitalization at $250 million and the Company's outstanding shares of common stock, which was 174,177,448 shares on July 9, 2020.

On February 17, 2021, the compensation committee of the board of directors and the board approved a cash bonus program of cash-settled stock appreciation right ("2021 SAR") awards and cash-settled performance stock unit ("2021 PSU") awards to the Company's employees. An aggregate of 2021 SAR awards with respect to 1,500,000 shares of common stock and 2021 PSU awards with respect to 1,500,000 shares of common stock were granted to the Company's employees. The 2021 SAR awards will be settled in cash, vest 33% on the first anniversary of the date of grant, and the remaining 67% monthly over the next 24 months, have a per-share base amount of $1.51, which was the closing sales price of a share of the Company's common stock on the grant date, and are in all cases subject to the terms and conditions of the Company's form of SAR award agreement. As of March 31, 2021, the performance conditions associated with the 2020 and 2021 PSU awards are not probable of achievement, and accordingly, no compensation expense has been recognized to date for these awards. Each SAR subject to a 2021 SAR award represents the right to a cash payment equal to the excess, if any, of (i) the fair market value of each underlying share of the Company's common stock, determined on the date of exercise of the 2021 SAR minus (ii) the base amount. Pursuant to the terms of the 2021 SAR awards, in no event may the cash payment for each SAR exceed $1.03, which is the maximum price per share of $2.54, minus the base amount of $1.51, subject to adjustment in accordance with the terms of the Stock Appreciation Right Award Agreement. The maximum price per share is the per-share value based on the Company's market capitalization at $600 million and the Company's outstanding shares of common stock, which was 236,512,391 shares on February 17, 2021.

The 2021 PSU awards vest 20% upon the initiation of a new clinical program with an in-licensed compound, 20% for reaching the recommended Phase 2 dose for any compound, 20% for the first patient enrolled in the expansion cohort of the Phase 1 ON123300 clinical trial, 20% for the first patient enrolled in a registrational study for any compound, and 20% for the topline data of a registrational study for any compound. The 2021 PSU awards have a maximum value of $2.54 per share. The maximum price per share is the per-share value based on the Company's approximate market capitalization at $350 million and the Company's outstanding shares of common stock, which was 236,512,391 shares on February 17, 2021. In all cases, the 2021 PSU awards are subject to the terms and conditions of the Company's form of PSU award agreement.

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

	Three months ended March 31, 2021
Risk-free interest rate	0.95%
Expected volatility	129.79%
Expected term	6.50 years
Expected dividend yield	0%
Weighted average grant date fair value	$ 0.04

During the three months ended March 31, 2021, the Company recognized $476,000 of compensation expense related to the SARs. Included in compensation expense related to SARs is $442,000 of expense resulting from the exercise of 2020 SARs during February 2021. As of March 31, 2021, the SARs liability was $57,000 and Is included in accrued expenses. As of March 31, 2021, there was $103,000 of unrecognized compensation cost related to the 2020 SARs and $44,000 of unrecognized compensation cost related to the 2021 SARs.

9. Research Agreements

The Company has entered into various licensing and right-to-sublicense agreements with educational institutions for the exclusive use of patents and patent applications, as well as any patents that may develop from research being conducted by such educational institutions in the field of anticancer therapy, genes and proteins. Results from this research have been licensed to the Company pursuant to these agreements. Under one of these agreements with Temple University ("Temple"), the Company is required to make annual maintenance payments to Temple and royalty payments based upon a percentage of sales generated from any products covered by the licensed patents, with minimum specified royalty payments. As no sales had been generated through March 31, 2020 under the licensed patents, the Company has not incurred any royalty expenses related to this agreement. In addition, the Company is required to pay Temple a percentage of any sublicensing fees received by the Company.

10. Related-Party Transactions

The Company entered into a research agreement, as subsequently amended, with the Mount Sinai School of Medicine ("Mount Sinai"), with which a former member of its board of directors and a stockholder is affiliated. The agreement expired in June 2020 and was not renewed. The board member left the Company's board in August 2020. Mount Sinai is undertaking research on behalf of the Company on the terms set forth in the agreements. Mount Sinai, in connection with the Company, will prepare applications for patents generated from the research. Results from all projects will belong exclusively to Mount Sinai, but the Company will have an exclusive option to license any inventions. Payments to Mount Sinai under this research agreement for the three months ended March 31, 2021 and 2020 were $0 and $124,000, respectively. At both March 31, 2021 and December 31, 2020, the Company had $77,000 payable to Mount Sinai under this agreement.

The Company entered into a consulting agreement with a member of its board of directors, which was cancelled in June 2020. The board member left the Company's board in August 2020. The former board member provided consulting services to the Company on the terms set forth in the agreement. Payments to this board member under this agreement for the three months ended March 31, 2021 and 2020 were $0 and $33,000, respectively. The Company had $0 payable under this agreement at both March 31, 2021 and December 31, 2020.

11. Securities Registrations and Sales Agreements

January 2020 Offering

On December 31, 2019, the Company entered into definitive securities purchase agreements with institutional investors for the issuance and sale in a registered direct offering of 27,662,518 shares of the Company's common stock at an offering price of $0.3615 per share.

Pursuant to the December 2019 HCW Engagement Letter, HCW agreed to serve as exclusive placement agent for the offering. In connection with the offering, the Company paid HCW an aggregate cash fee equal to 7.0% of the gross proceeds in the offering, management fee equal to 1.0% of the gross proceeds raised in the offering, $85,000 for non-accountable expenses; and $10,000 for clearing fees. The Company also issued to HCW or its designees placement agent warrant to purchase up to 1,383,126 shares of common stock at an exercise price of $0.4519 per share. The placement agent warrants are immediately exercisable and will expire on December 31, 2023.

The net proceeds to the Company from the offering, after deducting HCW's placement agent fees and expenses and other estimated offering expenses payable by the Company were approximately $9.0 million and were received in January 2020.

The offering was pursuant to a prospectus dated December 28, 2017, and a prospectus supplement dated as of December 31, 2019 to be filed in connection with a takedown from the Company's shelf registration statement on Form S-3 (File No. 333-221684). The offering closed on January 3, 2020.

January 7, 2021 Offering

On January 7, 2021, the Company entered into a purchase agreement with certain institutional and accredited investors for the sale of an aggregate of 19,551,124 shares of the Company’s common stock, at a purchase price of $0.445 per share.

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

In connection with the offering, pursuant to the purchase agreement we reimbursed Lincoln Park Capital Fund, LLC, as the lead investor (“Lincoln Park”), an aggregate of $100,000 for expenses incurred in connection with the offering, including any due diligence expenses and legal fees. Furthermore, pursuant to the purchase agreement, we have granted Lincoln Park certain rights to participate at fair value with other investors in up to 50% of the amount of any future offerings of common stock or securities exercisable for or convertible into common stock that the Company seeks to complete within one year after the closing of the offering, other than a firm commitment public offering.

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

The shares sold in the offering were offered and sold by the Company directly to the investors, without a placement agent, underwriter, broker or dealer, pursuant to an effective shelf registration statement on Form S-3 (File No. 333-237844) declared effective by the SEC on May 18, 2020, and the base prospectus contained therein. The offering closed on January 12, 2021.

February 10, 2021 Offering

On February 10, 2021, the Company entered into an underwriting agreement with Guggenheim Securities, LLC , as representative of several underwriters, for the public offering of 25,000,000 shares of the Company's common stock, at a public offering price of $1.00 per share. Under the terms of the underwriting agreement, the Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 3,750,000 shares of common stock at the same price. The option was exercised prior to closing.

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

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

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

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, 2020 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 18, 2021. 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 INSPIRE trial and other operations, and our ability to obtain sufficient funds on acceptable terms when needed, and our plans and future needs to scale back operations if adequate financing is not obtained;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials, including site initiation and patient enrollment, and regulatory approval of protocols for future clinical trials;
- our ability to enter into, maintain and perform collaboration agreements with other pharmaceutical companies, for funding and commercialization of our clinical product candidates or preclinical compounds, and our ability to achieve certain milestones under those agreements;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop, manufacture and commercialize our product candidates;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;

- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- recently enacted and future legislation and regulation regarding the healthcare system;
- the success of competing therapies and products that are or become available;
- our ability to maintain the listing of our securities on a national securities exchange;
- the potential for third party disputes and litigation;
- the performance of third parties, including contract research organizations ("CROs") and third-party manufacturers; and
- the impact of the novel coronavirus disease, COVID-19, to global economy and capital markets, and to our business and our financial results.

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

You should also read carefully the factors described in the "Risk Factors" in our most recent annual report on Form 10-K and quarterly reports on Form 10-Q, 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 targeted anti-cancer 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. ON 123300, multi-kinase inhibitor in solid tumors; and 2. oral rigosertib alone or in combination with PD-1 inhibitors for treatment of solid tumors. We are currently evaluating potential compounds for in-licensing opportunities.

Our net losses were $4.7 million and $5.1 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $433.3 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development of, and seek regulatory approval for, our product candidates, even if milestones under our license and collaboration agreements may be met. As of March 31, 2021, we had $48.0 million in cash and cash equivalents.

On January 12, 2021, we closed on an offering of common stock. We issued 19,551,124 shares of common stock. Net proceeds were approximately $8.5 million.

On February 16, 2021, we closed on an offering of common stock. We issued 28,750,000 shares of common stock. Net proceeds were approximately $26.7 million.

We believe that our cash and cash equivalents of $48.0 million, at March 31, 2021, will be sufficient to fund our operations and ongoing trials for more than eighteen months from the date of this filing. We do not have a recurring source of revenue to fund our operations and will need to raise additional funds to continue to develop and apply for regulatory approval for our drug candidates.

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

Product Candidates / Compounds

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

We believe based on data from preclinical studies, that ON 123300 has the potential to overcome the limitations of the current generation of approved cyclin dependent kinase (CDK 4/6) inhibitors. Pursuant to a license agreement with Temple University dated January 1, 1999 as amended March 21, 2013, we licensed compounds including ON 123300 from Temple University. ON 123300 monolactate (ON 123300) is a novel multi kinase inhibitor that targets both CDK4/6 as well as other tyrosine kinases believed to drive tumor proliferation. The below table depicts the half-maximal inhibitory concentration (IC_{50}) of ON 123300 and Palbociclib, which is a quantitative measure indicating the concentration of each drug needed to inhibit, in vitro, these listed kinases by 50%.

Kinase	ON 123300 IC_{50} (nM)	PALBOCICLIB IC_{50} (nM)
CDK 4/cyclin D1	3.87	5.36
CDK 6/cyclin D1	9.82	3.76
ARK 5	4.95	>5,000.00
FLT3	12.22	>10,000.00
FYN	11.09	>10,000.00
FMS	10.00	>10,000.00
PDGFRβ	26.00	>10,000.00
FGFR1	26.00	>10,000.00
ABL	53.32	>10,000.00
PI3K-δ	144.00	>10,000.00

· ON 123300 Investigator Brochure v1.

One such tyrosine kinase ARK5, also known as NUAK1, regulates AKT dependent cell survival and migration (perhaps involved with metastases) through inhibition of cellular metabolism. 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. We and our partner, HanX Biopharmaceuticals, Inc. (“HanX”), have recently initiated clinical studies to begin evaluating whether these findings from preclinical studies may translate to clinical activity or clinical benefit in cancer patients.

In certain in vitro models, the kinase inhibitory profile of ON 123300 had the highest activity against CDK4, CDK6, ARK5, FGFR1, PDGFRß and PI3K-δ, all of which are associated with the growth, survival and metastasis of human tumor cells (Reddy, 2014). In an in vitro investigation of ON 123300 against a broad spectrum of human tumor cell lines, ON 123300 displayed potent antiproliferative activity, with 50% growth inhibitory concentrations (GI50) ranging from 0.02 µM to 1.5 µM. In these in vitro models, ON 123300 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 ON 123300 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 ON 123300 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 ON 123300 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) and colorectal cancer (IBv.1 2020).

The effectiveness of first-generation non-selective CDK inhibitors (Selicilib/roscovitine and Alvocidib/ flavopiridol) in early trials was limited due to toxicities (Blachly 2013). Second-generation compounds (palbociclib, ribociclib and abemaciclib) specifically inhibit CDK4 and 6, thereby inhibiting retinoblastoma (RB) protein phosphorylation. 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 have recently been approved and are now standard of care in combination with hormonal therapy for patients with HR-positive, HER2-negative metastatic breast cancer.

In December 2017, we entered into a license and collaboration agreement with HanX, a company focused on development of novel oncology products, for the further development, registration and commercialization in China of ON 123300. Under the terms of the agreement, we received an upfront payment, and will receive regulatory and commercial milestone payments, as well as royalties on any future Chinese sales if the drug is approved. The key feature of the 2017 collaboration was that HanX provided all funding required for the Chinese Investigational New Drug Application (a "IND") thereby enabling the studies necessary in order to seek IND approval by the National Medical Products Administration (Chinese FDA). In the fourth quarter of 2019, HanX filed an IND with the Chinese FDA which was approved on January 6, 2020. We and HanX also intended for these studies underlying the Chinese IND approval, to meet the US Food and Drug Administration ("FDA") standards for IND approval. Accordingly, such studies were used by us for an IND filing with the US FDA. In September 2020, a Phase 1 Study with ON123300 in cancer patients was initiated in China. We maintain global rights to the study and study data outside of China.

Our IND submission to the US FDA was submitted in November 2020 and the FDA Study May Proceed letter was issued in December 2020. Enrollment into the US phase 1 study is anticipated to commence in the first half of 2021. The study will assess the safety, tolerability and pharmacokinetics of ON 123300 administered orally at increasing doses starting at 40 mg daily for consecutive 28-day cycles in patients (n=36) with relapsed/refractory advanced cancer, including but not limited to, patients with breast cancer that is resistant to approved second generation CDK 4/6 inhibitors as well as patients diagnosed with advanced Non-Hodgkin's lymphoma. In partnership with HanX, a complementary Phase 1 study 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. The first two dose cohorts have been completed and the third dose cohort is anticipated to start enrolling shortly. No dose limiting toxicities (DLT) have been observed to date. Collectively, these two Phase 1 studies are expected to provide data regarding the safety profile of ON 123300 and potentially preliminary efficacy signals in patients with advanced cancer.

Positive preclinical data was announced at the American Association for Cancer Research (AACR) annual meeting, which took place April 1-5, 2017 in Washington, DC, for ON 123300. We believe our CDK inhibitor is differentiated from other agents in the market or in development due to its multi-kinase inhibition.

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 inactivation of Rb by CDKs leads to malignant cell formation and occurs in the pathogenesis of most cancers. In a preclinical Retinoblastoma (Rb) positive xenograft model for breast cancer, ON 123300 activity was shown to be similar to palbociclib (Pfizer's Ibrance ®). Moreover, based on the same preclinical model, ON 123300 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 ($P< 0.05$) inhibitory effect on neutrophil counts when compared to ON 123300. These results would need to be replicated in clinical trials.

In vitro studies compared the growth inhibitory activity of ON 123300 and palbociclib in breast cancer cell lines with mutated or deleted RB, which demonstrated resistance to palbociclib but retained sensitivity towards ON 123300 (IBv.1 2020). Further analyses using mantle cell lymphoma cells indicated that ON 123300 was able to induce cell death via induction of apoptosis by inhibiting the AKT/PI3K pathway while palbociclib treatment was only able to induce cell cycle arrest due to the inhibition of CDK4/6 (Divakar, 2016). ON 123300 treatment was associated with the presence of several apoptotic markers (PARP, caspase 3, caspase 7 and caspase 9) and ON 123300 (but not palbociclib) led to the generation of apoptotic cells. Overall, apoptosis following ON 123300 exposure has been observed in the following cell lines: breast cancer (IBv.1 2020, Reddy, 2014), mantle cell lymphoma (Divakar, 2016), multiple myeloma (Perumal, 2016) and colorectal cancer (IBv.1 2020).

In addition to CDK4/6 and PI3 Kinase, ON 123300 may inhibit ARK5 (NUAK1) (IC50 of 4.95 nM) (IBv.1 2020, Reddy, 2014) while palbociclib does not. ARK5 is a member of the AMP -activated protein kinase (AMPK) family and is thought to function as a key regulator of cellular energy homeo-stasis (Liu, 2012) and is important in a number of cancer cell survival pathways. Overexpression of ARK5 is associated with poor prognosis in hepatocellular carcinoma (Cui, 2013), ovarian cancers (Phippen, 2016) 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) . ON 123300 inhibits ARK5 resulting in down regulation of the mTOR/MYC/RB1 pathways leading to cell cycle arrest and apoptosis.

Because ARK5 activity is now recognized as crucial in promoting cancer cell migration and invasion (Kusaki, 2004) the effect of ON 123300 treatment may have an impact on cell migration and wound healing. In certain in vitro models, ON 123300 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.1 2020). The ability of ON 123300 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 ON 123300 but not in the presence of palbociclib (IBv.1 2020).

The pathogenesis and progression of breast cancer is linked to C-Myc expression which is subsequently dependent on ARK5 activity. The inhibition of ARK5 has been shown to be lethal in MYC overexpressing tumors (Liu, 2012) and targeting ARK5 in the inhibitory profile of ON 123300 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 ON 123300 exposure (Reddy, 2014, Divakar, 2016, Perumal, 2016). Furthermore, ON 123300 has been tested in five murine xenograft models (breast cancer including triple negative disease, colorectal, 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.1 2020).

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 be used in combination with hormonal therapy. 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 ON 123300. This hypothesis needs to be proven in a clinical trial.

Unfortunately, mechanisms of acquired resistance are emerging with the approved CDK4/6 inhibitors leading to progression in patients with breast cancer (Spring, 2019; Knudsen, 2020). Therefore, the unmet medical need supports development of the next (third) generation CDK4/6 inhibitors in advanced HR+/HER- breast cancer. The inhibitory effect of ON 123300 may provide a therapeutic strategy to optimize efficacy of CDK 4/6 inhibition and reduce emergence of resistance.

ON 123300 has the most favorable IC50 value in comparison to the approved CDK4/6 inhibitors (palbociclib, ribociclib, and abemaciclib) and highest single agent cytotoxicity (Perumal, 2016, Divakar, 2016).

Based on data from continuous dosing studies in rats and monkeys the safety profile of ON 123300 is anticipated to be similar to 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 ON 123300, the unmet medical need of the advanced cancers potentially targeted by ON 123300 and the anticipated safety profile of ON 123300 as seen in pre-clinical studies, support conducting Phase 1 clinical studies.

Clinical development of ON 123300 for both breast cancer as well as other solid tumors in clinical trials is warranted based on the preclinical in vitro studies as well as the xenograft models. Onconova plans to advance testing whether ON 123300 will demonstrate improved activity and/or safety in patients with advanced malignancies.

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

We are currently supporting investigator-initiated studies that are exploring the use of rigosertib for cancers driven by mutated Ras genes including a Phase 1 study of rigosertib in combination with a PD-1 inhibitor for patients with progressive K-Ras mutated non-small cell lung cancer (NSCLC). The NSCLC study is open and continues to enroll patients. The objectives of this study are to identify the recommended Phase 2 dose (RP2D) for future studies and characterize the safety profile of the combination treatment. Results are expected in 2021. We anticipate, additional investigator initiated studies in RAS driven cancers in combination with PD-1 inhibitors, including in metastatic melanoma.

Oral Rigosertib as monotherapy

An investigator-initiated Phase 1b/2 study with rigosertib monotherapy in advanced squamous cell carcinoma associated with recessive dystrophic epidermolysis bullosa (RDEB-SCC) has enrolled its first patient.. A preclinical study is also currently investigating rigosertib in clear cell renal carcinoma (ccRCC).

Rare Disease Program in "RASopathies"

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

In January 2018, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), which is part of the National Institutes of Health (NIH). Under the terms of the CRADA, the NCI initiated and conducted preclinical laboratory studies on rigosertib in pediatric cancer associated RASopathies. As part of the CRADA, we provided rigosertib and initial funding towards the non-clinical studies. The NCI has conducted preclinical studies with cell lines from two pediatric solid tumors (rhabdomyosarcoma and neuroblastoma), including xenograft models. For both tumor cell lines, in vitro rigosertib exposure was associated with reduced cell viability associated with destabilization of microtubules, mitotic arrest and apoptosis. In a rhabdomyosarcoma xenograft model, rigosertib treatment delayed time to tumor progression and prolonged survival in the animals treated with rigosertib. (Kowalczyk, 2020)

Studies using leukemia cells from the rare childhood RASopathy, known as Juvenile Myelomonocytic Leukemia (JMML), have been conducted. In preliminary in vitro studies performed at Notable Labs, JMML cell killing was observed following rigosertib exposure. Murine xenograft studies performed at the University of California, San Francisco and funded through the Leukemia Lymphoma Society, evaluated rigosertib in this Ras-mutated disease. Further studies with JMML and rigosertib are under consideration.

COVID-19 Disease

In July 2020, based on initial in vitro data suggesting that rigosertib inhibited the replication of SARS-CoV-2 and rigosertib alone induces the dysregulation of RIG-I like receptor signaling (anti-viral defense pathway) and T cell exhaustion signaling in BW-90 cells (Silverman, Blood, Abstract # 4231, 2019), we submitted applications with the National Institute of Allergy and Infectious Disease (NIAID) and a separate application to the Biomedical Advanced Research and Development Authority (BARDA), with the goal of obtaining funding from the National Institutes of Health (NIH) to conduct human studies with rigosertib in COVID- 19 patients. Based on the reported mechanism of action which modulates the RAS/RAF/MEK/ERK pathway involved in proliferative signaling, we believe rigosertib may play an important role in inhibiting COVID-19 replication in human cells and specifically lung tissue, which is a primary source of serious disease. We await responses to these submissions. Subsequently, other laboratories have studied rigosertib in COVID-19 models but were unable to replicate the results of the initial study. These preclinical studies are continuing in additional laboratories. We do not currently plan to begin clinical trials of rigosertib in patients with COVID-19.

Critical Accounting Policies and Significant Judgments 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. We believe there have been no significant changes in our critical accounting policies as discussed in our annual report on Form 10-K filed with the SEC on March 18, 2021.

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

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

	Three Months ended March 31,		
	2021	2020	Change
Revenue	$ 56,000	$ 52,000	$ 4,000
Operating expenses:			
General and administrative	2,217,000	1,807,000	(410,000)
Research and development	1,937,000	3,370,000	1,433,000
Total operating expenses	4,154,000	5,177,000	1,023,000
Loss from operations	(4,098,000)	(5,125,000)	1,027,000
Change in fair value of warrant liability	(636,000)	(63,000)	(573,000)
Other income (expense), net	19,000	96,000	(77,000)
Net loss	$ (4,715,000)	$ (5,092,000)	$ 377,000

Revenues

Revenues increased by $4,000, or 8%, for the three months ended March 31, 2021 when compared to the same period in 2020 because of a clinical supply credit from SymBio in the 2021 period.

General and administrative expenses

General and administrative expenses increased by $0.4 million, or 23%, to $2.2 million for the three months ended March 31, 2021 from $1.8 million for the three months ended March 31, 2020. The increase was attributable primarily to $0.3 million of expenses for investor relations, proxy solicitation, and fees related to our special meeting by proxy in the 2021 period, and also to $0.1 million higher insurance expenses.

The details of our general and administrative expenses are:

	Three Months ended March 31,	
	2021	2020
Professional & consulting fees	$ 518,000	$ 522,000
Stock based compensation	56,000	45,000
Personnel related	778,000	758,000
Public company costs	532,000	188,000
Insurance & other	333,000	294,000
	$ 2,217,000	$ 1,807,000

Research and development expenses

Research and development expenses decreased by $1.4 million, or 43%, to $1.9 million for the three months ended March 31, 2021 from $3.4 million for the three months ended March 31, 2020. This decrease was caused primarily by $1.3 million lower clinical development and consulting expenses on the INSPIRE program in the 2021 period, and also by $0.1 million lower personnel and stock compensation expense during the 2021 period, following reductions in our workforce completed in the third and fourth quarter of 2020.

The details of our research and development expenses are:

	Three Months ended March 31,	
	2021	2020
Preclinical & clinical development	$ 567,000	$ 1,908,000
Personnel related	821,000	856,000
Manufacturing, formulation & development	155,000	60,000
Stock based compensation	9,000	47,000
Consulting fees	385,000	499,000
	$ 1,937,000	$ 3,370,000

Change in fair value of warrant liability

The fair value of the warrant liability increased $636,000 for the three months ended March 31, 2021, compared to an increase of $63,000 for the three months ended March 31, 2020. This change was caused by a larger increase in the 2021 period of the fair market value of the warrants issued in our rights offering in 2016.

Other income (expense), net

Other income (expense), net, was $19,000 for the three months ended March 31, 2021 and $96,000 for the three months ended March 31, 2020. The change of $77,000 was due to lower interest income in the 2021 period due to lower average cash balances, and higher foreign currency exchange losses in the 2021 period.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and experienced negative cash flows from our operations. We incurred net losses of $4.7 million and $5.1 million for the three months ended March 31, 2021 and 2020, respectively. Our operating activities used $6.6 million and $6.5 million of net cash during the three months ended March 31, 2021 and 2020, respectively. At March 31, 2021, we had an accumulated deficit of $433.3 million, working capital of $41.4 million, and cash and cash equivalents of $48.0 million. We believe that our cash and cash equivalents as of March 31, 2021, will be sufficient to fund our operations and ongoing trials for more than eighteen months from the date of this filing.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	**2020**
Net cash (used in) provided by:		
Operating activities	$ (6,648,000)	$ (6,463,000)
Investing activities	—	—
Financing activities	35,644,000	14,779,000
Effect of foreign currency translation	(16,000)	(6,000)
Net increase in cash and cash equivalents	$ 28,980,000	$ 8,310,000

Net cash used in operating activities

Net cash used in operating activities was $6.6 million for the three months ended March 31, 2021 and consisted primarily of a net loss of $4.7 million, including an increase in the fair value of warrant liability of $0.6 million, and $0.1 million of both noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $2.6 million. Significant changes in operating assets and liabilities included a decrease in prepaid expenses and other current assets of $0.1 million, a decrease in accounts payable and accrued liabilities of $2.7 million due to timing of invoices and payments to our vendors, and a decrease in deferred revenue of $0.1 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in operating activities was $6.5 million for the three months ended March 31, 2020 and consisted primarily of a net loss of $5.1 million, including an increase in the fair value of warrant liability of $0.1 million, and $0.1 million of both noncash stock-based compensation and depreciation expense. Changes in operating assets and liabilities resulted in a net decrease in cash of $1.5 million. Significant changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of $0.1 million, a decrease in accounts payable and accrued liabilities of $1.4 million due to timing of invoices and payments to our vendors, and a decrease in deferred revenue of $0.1 million due to recognition of the unamortized portion of the upfront payment under our collaboration agreement with SymBio.

Net cash used in investing activities

There was no cash used in investing activities during the three months ended March 31, 2021 and 2020.

Net cash provided by financing activities

Net cash provided by financing activities was $35.6 million and $14.8 million for the three months ended March 31, 2021 and 2020, respectively. The net cash provided by financing activities in the 2021 period resulted from proceeds received from the sales of common stock and the exercise of warrants. The net cash provided by financing activities in the 2020 period resulted from the sale of common stock and the exercise of warrants.

Operating and Capital Expenditure Requirements

We believe that our cash and cash equivalents of $48.0 million at March 31, 2021, will be sufficient to fund our operations and ongoing trials for more than eighteen months from the date of this filing. The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our net cash expenditures in 2021 to be lower than they were in 2020, due primarily to the INSPIRE study being completed in 2020, reductions in our workforce during 2020, and having an earlier clinical stage, and therefore less expensive to develop, pipeline in 2021. The nature, design, size, and cost of further studies will depend in large part on the outcome of ongoing studies, discussions with regulators, and the potential in-license of any additional compounds or product candidates.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Managements' Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of March 31, 2021, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officers, evaluated any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive and principal financial officers concluded that no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2021 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

The following risk factor should be read in conjunction with the "Risk Factors" previously disclosed in our annual report on Form 10-K filed with the SEC on March 18, 2021.

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. On October 6, 2020, we received a letter from the Nasdaq Capital Market indicating that we failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2).

Nasdaq Listing Rule 5550(a)(2) requires that companies listed on the Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share. Under Nasdaq Listing Rule 5810(c)(3)(A), we had a 180 calendar day grace period, or until April 5, 2021, to regain compliance by meeting the continued listing standard. The continued listing standard is 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. On February 23, 2021, we received notice from Nasdaq that we had regained compliance with the minimum bid price requirement because the Company's common stock had a closing price of at least $1.00 per share for 10 consecutive business days. Subsequently, the closing price of the Company's common stock has decreased below $1.00 per share.

On May 11, 2021, we received a letter from the Nasdaq Capital Market indicating that we failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2) for the period from March 29, 2021 to May 10, 2021.

If we are not in compliance by November 8, 2021, 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 the Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify the Nasdaq Capital Market 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 maintain compliance with the minimum bid price requirement or will otherwise be in compliance with other the Nasdaq Capital Market listing criteria. If we are unable to maintain compliance with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, making it 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.

The COVID-19 pandemic could adversely impact our business, including our clinical trials, drug manufacturing and nonclinical activities.

As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, clinical trials, drug manufacturing and nonclinical activities. These potential disruptions may include but are not limited to delays or difficulties in clinical site initiation and patient recruitment, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, study modification, suspension, or termination, the introduction of remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes requiring state licensing, study deviations or noncompliance, diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, IRBs, and the FDA. The foregoing may also impact the integrity of our study data. The effects of the COVID-19 pandemic may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects.

The COVID-19 pandemic may also impact our ability to obtain supplies of our product candidates or other materials that may be necessary for the conduct of our development program. If any of our suppliers are adversely impacted by the COVID-19 pandemic or the restrictions resulting from the outbreak, if they cannot obtain the necessary supplies, or if such third parties need to prioritize other products or customers over us, including under the Defense Production Act, we may experience delays or disruptions in our supply chain, which could have a material and adverse impact on our business. Third party manufacturers may also need to implement measures and changes, or deviate from typical requirements because of the COVID-19 pandemic that may otherwise adversely impact our supply chains or the quality of the resulting products or supplies. Depending on the change, we may need to obtain FDA pre-approval or otherwise provide FDA with a notification of the change.

The pandemic could further impact our ability to interact with the FDA or other regulatory authorities and obtain any necessary inspections. Due to the potential impact of the COVID -19 outbreak on clinical trials, drug development, and manufacturing, FDA issued a number of guidance documents concerning how sponsors and investigators may address these challenges. FDA has also issued guidance on the development of products to treat COVID-19. FDA's guidance is continually evolving.

The COVID-19 pandemic may also result in changes in laws and regulations. By example, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which includes various provisions regarding FDA drug shortage reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. This and any future changes in law may require that we change our internal processes and procedures to ensure continued compliance.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 may impact our business, including our drug manufacturing, nonclinical activities, clinical trials and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Description
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Principal Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
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

EXHIBIT INDEX

Exhibit Number	Description
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31.2	Rule 13a-14(a)/15d-14(a) Certifications of Principal Financial Officer
32.1	Section 1350 Certifications of Principal Executive Officer
32.2	Section 1350 Certifications of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
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SIGNATURES

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

ONCONOVA THERAPEUTICS, INC.

Dated: May 17, 2021

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

Dated: May 17, 2021

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

Exhibit 31.1

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

I, Steven Fruchtman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: May 17, 2021

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

Exhibit 31.2

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

I, Mark Guerin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: May 17, 2021

/s/ Mark Guerin

Mark Guerin
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven Fruchtman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Dated: May 17, 2021

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

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

Exhibit 32.2

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

In connection with the Quarterly Report of Onconova Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Guerin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Dated: May 17, 2021

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

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