

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36304

Phio Pharmaceuticals Corp.
(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

45-3215903
(I.R.S. Employer
Identification No.)

257 Simarano Drive, Suite 101, Marlborough, MA 01752
(Address of principal executive office) (Zip code)

Registrant's telephone number: (508) 767-3861

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value, \$0.0001 per share	PHIO	The Nasdaq Capital Market

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 time that the registrant was required to submit such files). Yes No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 7(a)(2)(B) of the Securities Act.

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

As of November 6, 2020, Phio Pharmaceuticals Corp. had 5,780,592 shares of common stock, \$0.0001 par value, outstanding.

PHIO PHARMACEUTICALS CORP.
FORM 10-Q — QUARTER ENDED SEPTEMBER 30, 2020

INDEX

Part No.	Item No.	Description	Page No.
I		<u>FINANCIAL INFORMATION</u>	
	1	<u>Financial Statements (Unaudited)</u>	3
		<u>Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019</u>	3
		<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2020 and 2019</u>	4
		<u>Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2020 and 2019</u>	5
		<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2020 and 2019</u>	6
		<u>Notes to Condensed Consolidated Financial Statements</u>	7
	2	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
	3	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
	4	<u>Controls and Procedures</u>	25
II		<u>OTHER INFORMATION</u>	26
	1	<u>Legal Proceedings</u>	26
	1A	<u>Risk Factors</u>	26
	2	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
	3	<u>Defaults Upon Senior Securities</u>	29
	4	<u>Mine Safety Disclosures</u>	29
	5	<u>Other Information</u>	29
	6	<u>Exhibits</u>	29
		<u>Signatures</u>	30

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PHIO PHARMACEUTICALS CORP.
 CONDENSED CONSOLIDATED BALANCE SHEETS
 (Amounts in thousands, except share and per share data)
 (Unaudited)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash	\$ 16,868	\$ 6,934
Restricted cash	50	50
Prepaid expenses and other current assets	702	316
Total current assets	17,620	7,300
Right of use asset	428	511
Property and equipment, net	173	210
Other assets	18	18
Total assets	<u>\$ 18,239</u>	<u>\$ 8,039</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 742	\$ 809
Accrued expenses and other current liabilities	1,375	964
Lease liability	113	107
Total current liabilities	2,230	1,880
Lease liability, net of current portion	325	411
Long-term debt	231	—
Total liabilities	<u>2,786</u>	<u>2,291</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized	—	—
Common stock, \$0.0001 par value, 100,000,000 shares authorized; 5,780,533 and 669,433 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	116,603	100,566
Accumulated deficit	(101,151)	(94,819)
Total stockholders' equity	<u>15,453</u>	<u>5,748</u>
Total liabilities and stockholders' equity	<u>\$ 18,239</u>	<u>\$ 8,039</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	\$ —	\$ —	\$ —	\$ 21
Operating expenses:				
Research and development	1,256	1,042	3,253	3,277
General and administrative	1,050	1,071	3,078	3,062
Total operating expenses	<u>2,306</u>	<u>2,113</u>	<u>6,331</u>	<u>6,339</u>
Operating loss	(2,306)	(2,113)	(6,331)	(6,318)
Total other (expense) income, net	(3)	19	(1)	70
Net loss	<u>\$ (2,309)</u>	<u>\$ (2,094)</u>	<u>\$ (6,332)</u>	<u>\$ (6,248)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.40)</u>	<u>\$ (4.53)</u>	<u>\$ (1.51)</u>	<u>\$ (14.70)</u>
Weighted average shares: basic and diluted	<u>5,780,386</u>	<u>461,990</u>	<u>4,181,862</u>	<u>424,910</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share data)
(Unaudited)

For the Three and Nine Months Ended September 30, 2020

	Common Stock		1	Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2019	669,433	\$	1	\$ 100,566	\$ (94,819)	\$ 5,748
Issuance of common stock under employee stock purchase plan	153		–	1	–	1
Cash in lieu of fractional shares for 1:55 reverse stock split	(1,364)		–	(15)	–	(15)
Issuance of common stock and warrants in connection with registered direct and private placement offerings, net of offering costs of \$273	197,056		–	1,467	–	1,467
Issuance of common stock, pre-funded warrants and warrants in connection with underwritten public offering, net of offering costs of \$906	993,633		–	7,093	–	7,093
Issuance of common stock upon the exercise of warrants	1,006,367		–	1	–	1
Issuance of common stock upon vesting of restricted stock units	2,573		–	(2)	–	(2)
Stock-based compensation expense	–		–	43	–	43
Net loss	–		–	–	(2,351)	(2,351)
Balance at March 31, 2020	2,867,851		1	109,154	(97,170)	11,985
Issuance of common stock and warrants in connection with registered direct and private placement offerings, net of offering costs of \$473	1,713,064		–	3,527	–	3,527
Issuance of common stock upon the exercise of warrants	1,199,296		–	3,863	–	3,863
Issuance of common stock upon vesting of restricted stock units	15		–	–	–	–
Stock-based compensation expense	–		–	30	–	30
Net loss	–		–	–	(1,672)	(1,672)
Balance at June 30, 2020	5,780,226		1	116,574	(98,842)	17,733
Offering costs related to the exercise of warrants	–		–	(8)	–	(8)
Issuance of common stock upon vesting of restricted stock units	307		–	–	–	–
Stock-based compensation expense	–		–	37	–	37
Net loss	–		–	–	(2,309)	(2,309)
Balance at September 30, 2020	5,780,533	\$	1	\$ 116,603	\$ (101,151)	\$ 15,453

For the Three and Nine Months Ended September 30, 2019

	Common Stock		1	Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2018	342,578	\$	–	\$ 99,489	\$ (85,911)	\$ 13,578
Issuance of common stock upon the exercise of warrants	78,260		–	43	–	43
Issuance of restricted stock	4,419		–	–	–	–
Stock-based compensation expense	–		–	160	–	160
Net loss	–		–	–	(2,119)	(2,119)
Balance at March 31, 2019	425,257		–	99,692	(88,030)	11,662
Issuance of common stock upon the exercise of warrants	30,910		–	17	–	17
Issuance of common stock under the employee stock purchase plan	36		–	1	–	1
Stock-based compensation expense	–		–	62	–	62
Net loss	–		–	–	(2,035)	(2,035)
Balance at June 30, 2019	456,203		–	99,772	(90,065)	9,707
Issuance of common stock under Lincoln Park Capital, LLC purchase agreement, net of offering costs of \$52	9,090		–	(52)	–	(52)
Issuance of common stock upon vesting of restricted stock units	1,154		–	(3)	–	(3)
Stock-based compensation expense	–		–	47	–	47
Net loss	–		–	–	(2,094)	(2,094)
Balance at September 30, 2019	466,447	\$	–	\$ 99,764	\$ (92,159)	\$ 7,605

The accompanying notes are an integral part of these condensed consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (6,332)	\$ (6,248)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	55	51
Non-cash lease expense	83	82
Non-cash stock-based compensation	110	269
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(386)	(330)
Accounts payable	(67)	306
Accrued expenses and other liabilities	438	(151)
Lease liability	(80)	(78)
Net cash used in operating activities	(6,179)	(6,099)
Cash flows from investing activities:		
Cash paid for purchase of property and equipment	(18)	(77)
Net cash used in investing activities	(18)	(77)
Cash flows from financing activities:		
Net proceeds from the issuance of common stock and warrants	12,087	–
Net proceeds from the exercise of warrants	3,856	60
Financing costs from the issuance of common stock under Lincoln Park Capital, LLC purchase agreement	–	(52)
Proceeds from the issuance of common stock in connection with the employee stock plan	1	1
Cash paid in lieu of fractional shares for 1:55 reverse stock split	(15)	–
Proceeds from debt	231	–
Payments of taxes for net share settled restricted stock unit issuances	(2)	(3)
Payments of capital lease obligations less than one year	(27)	–
Net cash provided by financing activities	16,131	6
Net increase (decrease) in cash and restricted cash	9,934	(6,170)
Cash and restricted cash at the beginning of period	6,984	14,929
Cash and restricted cash at the end of period	<u>\$ 16,918</u>	<u>\$ 8,759</u>
Supplemental disclosure of non-cash investing and financing activities:		
Right of use asset obtained in exchange for operating lease liability	\$ –	\$ 620
Acquisition of property and equipment included in accrued expenses and other current liabilities	\$ –	\$ 33

The accompanying notes are an integral part of these condensed consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of Operations

Phio Pharmaceuticals Corp. (“**Phio**,” “**we**,” “**our**” or the “**Company**”) is a biotechnology company developing the next generation of immuno-oncology therapeutics based on its self-delivering RNAi (“**INTASYL™**”) therapeutic platform. The Company's efforts are focused on silencing tumor-induced suppression of the immune system through its proprietary INTASYL platform with utility in immune cells and the tumor micro-environment. The Company's goal is to develop powerful INTASYL therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby potentially providing patients a powerful new treatment option that goes beyond current treatment modalities.

2. Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America (“**GAAP**”). Certain information and footnote disclosures included in the Company's annual financial statements have been condensed or omitted. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. In the opinion of management, all adjustments (including normal recurring accruals) considered necessary for a fair presentation of the condensed consolidated financial statements have been included. Interim results are not necessarily indicative of results for a full year.

Reverse Stock Split

Effective January 15, 2020, the Company completed a 1-for-55 reverse stock split of the Company's outstanding common stock. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital. Unless otherwise noted, shares of common stock issued and outstanding, shares underlying warrants and stock awards, shares reserved, conversion price of convertible securities, exercise prices of warrants and stock awards and loss per share have been proportionately adjusted to reflect the reverse stock split. The reverse stock split did not reduce the number of authorized shares of the Company's common stock or preferred stock.

Principles of Consolidation

The consolidated financial statements include the accounts of Phio and its wholly-owned subsidiary, MirImmune, LLC. All material intercompany accounts have been eliminated in consolidation.

Risks and Uncertainties

In December 2019, a novel strain of coronavirus, causing COVID-19, was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States. In March 2020, the World Health Organization declared the outbreak a pandemic. We have not yet experienced any significant impacts or interruptions to our financial condition or operations as a result of the coronavirus pandemic at this time, but have begun to see our third party suppliers and service providers on which we rely becoming impacted, presumably as a result of the pandemic. Without a significant and sustained improvement of the current situation, we may experience significant and longer lasting impacts to certain of our development activities outsourced to third-party service providers. If the measures to contain the outbreak continue or are extended, it may have a more significant effect on our operations and those of third parties on which we rely, including reducing the availability of supplies that we purchase, closures of or delays in businesses that we rely on to provide services and to conduct preclinical and clinical activities for our product candidates and disrupting the supplies and services we rely on for the development of our product candidates. Additionally, a long lasting pandemic may adversely affect future clinical trial initiations and participant recruitment and enrollments, all of which may in turn slow, delay or pause our research and development activities. The ultimate impact of the coronavirus pandemic is highly uncertain and subject to change, and certain of our business operations may be delayed. The Company does not yet know the full extent of such potential delays or impacts on its business and preclinical and clinical trial activities. Moreover, the pandemic creates uncertainty around our ability to access capital markets and raise additional working capital that we will need to sustain our operations over the long term, particularly if the impacts of the pandemic are long lasting and affect us and our vendors and contractors.

Coronavirus Aid, Relief, and Economic Security Act

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the “**CARES Act**”) was enacted. The CARES Act is an emergency economic stimulus package passed in response to the coronavirus outbreak that includes, but is not limited to, provisions providing aid to small businesses in the form of loans and grants and numerous tax provisions such as certain payroll tax benefits, changes to the net operating loss rules, and the business interest expense deduction rules. On May 11, 2020, the Company received loan proceeds pursuant to the Paycheck Protection Program (the “**PPP**”) under the CARES Act. On June 5, 2020, President Trump signed into law the Paycheck Protection Program Flexibility Act of 2020 (the “**Flexibility Act**”), which amends the PPP created by the CARES Act. The Flexibility Act revises certain terms and provisions of the PPP to address issues raised by eligible borrowers adversely impacted by the ongoing COVID-19 pandemic. Refer to footnote 6 for further details. The Company does not expect the provisions outside of the PPP in the CARES Act to have a material impact on its condensed consolidated financial statements. As there continues to be updates to the provisions under the CARES Act, the Company will continue to assess the potential impacts on our business, results of operations and financial statements.

Uses of Estimates in Preparation of Financial Statements

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The areas subject to significant estimates and judgement include, among others, those related to the fair value of equity awards, research and development expenses, right of use lease assets, the fair value of financial instruments, useful lives of property and equipment, income taxes, and our valuation allowance on our deferred tax assets. On an ongoing basis we evaluate our estimates and base our estimates on historical experience and other relevant assumptions that we believe are reasonable under the circumstances, including as a result of new information that may emerge concerning the coronavirus pandemic. We have made estimates of the impact of the coronavirus pandemic within our financial statements and there may be changes to those estimates in future periods. Actual results could differ materially from these estimates.

Restricted Cash

Restricted cash consists of certificates of deposit held by financial institutions as collateral for the Company’s corporate credit cards.

Leases

In connection with the adoption on January 1, 2019, the Company follows the provisions of the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“ASC”) Topic 842, “Leases” (“ASC 842”). At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. For contracts that contain a lease, the Company identifies the lease and non-lease components, determines the consideration in the contract and recognizes the classification of the lease as operating or financing. At the commencement date of the lease, the Company recognizes a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term.

The Company has elected the package of practical expedients to not reassess its prior conclusions about lease identification, lease classification and indirect costs and to not separate lease and non-lease components. The Company has elected not to recognize on the balance sheet leases with a term less than one year.

Lease liabilities and the corresponding right of use assets are recorded based on the present value of lease payments to be made over the lease term. The discount rate used to calculate the present value is the rate implicit in the lease, or if not readily determinable, the Company’s incremental borrowing rate. The Company’s incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right of use asset may be required for items such as initial direct costs or incentives received. Lease payments on operating leases are recognized on a straight-line basis over the expected term of the lease. Lease payments on financing leases are recognized using the effective interest method.

Derivative Financial Instruments

The Company follows the provisions of the FASB ASC Topic 815, “Derivatives and Hedging” (“ASC 815”). Financial instruments that meet the definition of a derivative are classified as an asset or liability and measured at fair value on the issuance date and are revalued on each subsequent balance sheet date. The changes in fair value are recognized as current period income or loss. Financial instruments that do not meet the definition of a derivative are classified as equity and measured at fair value and recorded as additional paid-in capital in stockholders’ equity at the date of issuance. No further adjustments to their valuation are made.

Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for restricted cash, prepaid expenses, accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Research and Development Expenses

Research and development expenses relate to compensation and benefits for research and development personnel, facility-related expenses, supplies, external services, costs to acquire technology licenses, expenses associated with preclinical and clinical development activities and other operating costs. Research and development expenses are charged to expense as incurred. Payments made by the Company in advance for research and development services not yet provided and/or for materials not yet received are recorded as prepaid expenses and expensed when the service has been performed or when the goods have been received. Accrued liabilities are recorded related to those expenses for which vendors have not yet billed the Company with respect to services provided and/or materials that it has received.

The Company contracts with third parties to perform various preclinical and clinical activities on its behalf for the continued development of its product candidates. Accruals and expenses are recorded during the period incurred based on such estimates and assumptions as expected cost, passage of time, the achievement of milestones and other information available to us and are assessed on a quarterly basis. Actual results may differ from these estimates and could have a material impact on the Company's reported results. The Company's historical accrual estimates have not been materially different from its actual costs.

Stock-based Compensation

The Company follows the provisions of the FASB ASC Topic 718, "*Compensation — Stock Compensation*" ("**ASC 718**"), which requires the measurement and recognition of compensation expense for all stock-based payment awards. Stock-based compensation expense is based on the grant date fair value estimated in accordance with the provisions of ASC 718 and is recognized as an expense over the requisite service period.

Comprehensive Loss

The Company's comprehensive loss is equal to its net loss for all periods presented.

Net Loss per Share

The Company accounts for and discloses net loss per share in accordance with the FASB ASC Topic 260, "*Earnings per Share.*" Basic and diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing the Company's net loss by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares.

3. Liquidity and Going Concern

The Company has reported recurring losses from operations since inception and expects that the Company will continue to have negative cash flows from operations for the foreseeable future. Historically, the Company's primary source of funding has been the sale of its securities. The Company's ability to continue to fund its operations is dependent on obtaining funding from third parties, such as proceeds from the issuance of debt, sale of equity, or strategic opportunities, in order to maintain its operations. This is dependent on a number of factors, including the market demand or liquidity of the Company's common stock. There is no guarantee that debt, additional equity or other funding will be available to us on acceptable terms, or at all. Moreover, the global coronavirus pandemic has led to significant uncertainty and increased volatility in the capital markets. While the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict, if these conditions in the capital markets continue for an extended period of time it may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to complete our planned preclinical and clinical studies on a timely basis, or at all. The ultimate impact of the coronavirus pandemic on our liquidity is highly uncertain and subject to change. While we anticipate that we may experience a continued impact to our research and development activities, we do not yet know the full extent of potential delays or the impact on our business, financial condition, or our preclinical and clinical trial activities. There may be developments outside of our control that require us to adjust our operating plans and given the nature of the situation, we cannot reasonably estimate the impact of the coronavirus on our financial condition, results of operations or cash flows in the future. If we fail to obtain additional funding when needed, we would be forced to scale back or terminate our operations or seek to merge with or to be acquired by another company.

While we believe that the coronavirus pandemic has not had a significant impact on our financial condition and results of operations at this time, the extent to which the coronavirus pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus pandemic and the actions to contain the coronavirus or treat its impact, among others. The Company believes that its existing cash, should be sufficient to fund operations for at least the next 12 months from the date of the release of these financial statements.

4. Recent Accounting Pronouncements

In November 2018, the FASB issued Accounting Standards Update (“ASU”) 2018-18, “*Collaborative Arrangements (Topic 808)*” (“**Topic 808**”), which clarifies the interaction between Topic 808 and ASC Topic 606, “*Revenue from Customers*.” The update provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under ASC Topic 606 and provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. This ASU is effective for annual reporting periods beginning after December 15, 2019, including interim periods within that reporting period. This guidance is required to be applied retrospectively to the date of adoption of ASC Topic 606. The Company adopted ASC Topic 606 in the first quarter of 2018 and adopted ASU 2018-18 in the first quarter of 2020. The Company also elected to apply ASU 2018-18 only to contracts that were not completed at the date of initial application of Topic 606. Since the Company has no significant revenue, this ASU has no immediate impact on its condensed consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, “*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*.” The amendments in the update simplify the accounting for income taxes by eliminating the exceptions related to the incremental approach for intraperiod tax allocation, the recognition of a deferred tax liability for equity method investments, not recognizing a deferred tax liability for a foreign subsidiary and the general methodology for calculating income taxes in an interim period. The amendments also clarify and simplify other aspects of the accounting for income taxes. The amendments in ASU 2019-12 are effective for public entities for fiscal years, and the interim periods within those fiscal years, beginning after December 20, 2020. Early adoption is permitted. The Company is evaluating the expected impact this guidance may have on the consolidated financial statements and related disclosures.

5. Leases

On January 22, 2019, the Company amended the lease for its corporate headquarters and primary research facility in Marlborough, Massachusetts. The Company leases 7,581 square feet of office and laboratory space, which will expire on March 31, 2024. The lease contains an option to terminate the lease after two years or three years by providing advance written notice of termination pursuant to the terms of the agreement. The exercise of this option was not determined to be reasonably certain and thus is not included in the lease liability on the Company’s balance sheet.

The lease for our corporate headquarters represents substantially all of our significant lease obligations. The amounts reported in the condensed consolidated balance sheets for operating leases in which the Company is the lessee and other supplemental balance sheet information is set forth as follows, in thousands, except lease term and discount rate:

	September 30, 2020	December 31, 2019
Assets		
Right of use asset	\$ 428	\$ 511
Liabilities		
Lease liability, current	113	107
Lease liability, non-current	325	411
Total lease liability	<u>\$ 438</u>	<u>\$ 518</u>
Lease Term and Discount Rate		
Weighted average remaining lease term	3.83	4.43
Weighted average discount rate	4.70%	4.64%

Operating lease cost included in operating expense was \$33,000 and \$33,000 for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, operating lease cost included in operating expense was \$99,000 and \$94,000, respectively. Short-term lease costs were not material for the three and nine months ended September 30, 2020 and 2019.

Cash paid for the amounts included in the measurement of the operating lease liability on the Company's condensed consolidated balance sheets and included within changes in the lease liability in the operating activities of our condensed consolidated statement of cash flows was \$32,200 and \$31,000 for the three months ended September 30, 2020 and 2019, respectively, and \$95,600 and \$90,000 for the nine months ended September 30, 2020 and 2019, respectively.

Future lease payments for our non-cancellable operating leases and a reconciliation to the carrying amount of the operating lease liability presented in the condensed consolidated balance sheet as of September 30, 2020 is as follows, in thousands:

2020 (remaining)	\$	32
2021		132
2022		135
2023		140
2024		35
Total lease payments		474
Less: Imputed interest		(36)
Total operating lease liabilities (includes current portion)	\$	<u>438</u>

6. Debt

On May 11, 2020, the Company received loan proceeds in the amount of \$231,252 from Bank of America, N.A., as lender, pursuant to the PPP under the CARES Act. The PPP loan matures on May 11, 2022 and bears interest at a rate of 1% per year. The loan may be forgiven if used for eligible purposes, including payroll, benefits, rent and utilities. Under the Flexibility Act, the definition of a covered period for which a borrower must spend the PPP loan proceeds in order to be eligible for PPP loan forgiveness is the earlier of the date that is 24-weeks (or eight-weeks at the borrower's option) from the date the loan was funded or December 31, 2020. Additionally, monthly principal and interest payments are deferred until the date on which the determination of PPP loan forgiveness is remitted to the lender, or 10 months after the end of the loan forgiveness covered period. Payment terms if the PPP loan is not forgiven are not known at this time.

The Company carefully assessed the requirements for application under the PPP and believes that the loan is necessary to support its operations. The Company intends to apply for loan forgiveness, but as loan forgiveness has not yet been determined the Company followed the guidance under the FASB ASC Topic 470, "Debt" ("ASC 470") in assessing the accounting for the PPP loan proceeds. Per ASC 470, the Company recorded a liability on the balance sheet for the full amount of PPP loan proceeds received and will accrue interest over the term of the loan. As of September 30, 2020, the PPP loan proceeds have been classified as long-term debt on the balance sheet.

7. Stockholders' Equity

February 2020 Registered Direct Offering and Private Placement — On February 6, 2020, the Company completed a registered direct offering (the “**February 2020 Registered Offering**”) of 197,056 shares of the Company’s common stock at a purchase price of \$8.705 per share and in a concurrent private placement, sold warrants to purchase an aggregate of 197,056 shares of the Company’s common stock at a purchase price of \$0.125 per underlying warrant share and with an exercise price of \$8.71 per share. Net proceeds to the Company from the February 2020 Registered Offering were \$1,467,000 after deducting placement agent fees and offering expenses paid by the Company. In connection with the February 2020 Registered Offering, the Company also issued warrants to purchase a total of 14,779 shares of the Company’s common stock with an exercise price of \$11.0375 per share to the placement agent, H.C. Wainwright & Co., LLC (“**HCW**”).

February 2020 Underwritten Public Offering — On February 13, 2020, the Company completed an underwritten public offering of 993,633 shares of the Company’s common stock and pre-funded warrants (the “**2020 Pre-Funded Warrants**”) to purchase an aggregate of 1,006,367 shares of the Company’s common stock (the “**February 2020 Underwritten Offering**”). The 2020 Pre-Funded Warrants were immediately exercisable at an exercise price per share of \$0.001. Each share of Company common stock or 2020 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase one share of Company common stock at an exercise price of \$4.00 per share (the “**February 2020 Warrants**”). The combined public offering price was \$4.00 per Company common stock unit or \$3.999 per 2020 Pre-Funded Warrant unit. Net proceeds from the February 2020 Underwritten Offering were \$7,093,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company.

The Company also granted HCW, as underwriter, a 30-day option (the “**Option**”) to purchase up to an additional 300,000 shares of Company common stock and/or February 2020 Warrants to purchase up to an aggregate of 300,000 shares of Company common stock. On February 12, 2020, HCW partially exercised the Option to purchase an aggregate of 300,000 additional February 2020 Warrants at a public offering price per option warrant of \$0.001.

Additionally, pursuant to the February 2020 Underwritten Offering, the Company issued warrants to purchase up to 150,000 shares of Company common stock, immediately exercisable at an exercise price of \$5.00 per share to HCW, as underwriter.

April 2020 Registered Direct Offering and Private Placement — On April 2, 2020, the Company completed a registered direct offering (the “**April 2020 Offering**”) of 1,713,064 shares of the Company’s common stock at a purchase price of \$2.21 per share and in a concurrent private placement, sold warrants to purchase an aggregate of 1,713,064 shares of the Company’s common stock at a purchase price of \$0.125 per underlying warrant share and with an exercise price of \$2.21 per share. Net proceeds to the Company from the April 2020 Offering were \$3,527,000 after deducting placement agent fees and offering expenses paid by the Company. In connection with the April 2020 Offering, the Company also issued warrants to purchase a total of 128,480 shares of the Company’s common stock with an exercise price of \$2.9188 per share to the placement agent, HCW.

Warrants

The Company first assesses the warrants it issues under the FASB ASC Topic 480, “*Distinguishing Liabilities from Equity*” (“**ASC 480**”) to determine whether they are within the scope of ASC 480. As there are no instances outside of the Company’s control that could require cash settlement of the warrants, including the warrants issued by the Company during the nine months ended September 30, 2020, the Company’s outstanding warrants are outside the scope of ASC 480.

The Company then applies and follows the applicable accounting guidance in ASC 815. Financial instruments are accounted for as either derivative liabilities or as equity instruments depending on the specific terms of the agreement. The Company’s outstanding warrants do not meet the definition of a derivative instrument as they are indexed to the Company’s common stock and classified within stockholders’ equity. Based on this determination, the Company’s warrants issued in the February 2020 Registered Offering, February 2020 Underwritten Offering, April 2020 Offering, as well as all of the Company’s remaining outstanding warrants, are classified within stockholders’ equity.

The following table summarizes the Company's outstanding equity-classified warrants at September 30, 2020:

Description	Exercise Price	Expiration Date	Balance	Warrants Issued	Warrants Exercised	Warrants Expired	Balance
			December 31, 2019				September 30, 2020
June 2015 Warrants	\$ 2,860.00	6/2/2020	2,364	–	–	(2,364)	–
December 2016 Warrants	\$ 495.00	12/21/2021	23,233	–	–	–	23,233
April 2018 Warrants	\$ 173.25	5/31/2023	20,599	–	–	–	20,599
April 2018 Placement Agent Warrants	\$ 223.00	4/9/2023	1,373	–	–	–	1,373
October 2018 Warrants	\$ 10.45	10/3/2025	389,610	–	–	–	389,610
October 2018 Underwriter Warrants	\$ 13.06	10/1/2023	29,220	–	–	–	29,220
November 2019 Placement Agent Warrants	\$ 6.875	11/18/2024	13,636	–	–	–	13,636
February 2020 Registered Direct Warrants	\$ 8.71	8/6/2025	–	197,056	–	–	197,056
February 2020 Placement Agent Warrants	\$ 11.0375	2/4/2025	–	14,779	–	–	14,779
February 2020 Underwritten Offering Warrants	\$ 4.00	2/13/2025	–	2,300,000	(973,500)	–	1,326,500
February 2020 Pre-funded Warrants	\$ 0.001	No expiration	–	1,006,367	(1,006,367)	–	–
February 2020 Underwriter Warrants	\$ 5.00	2/11/2025	–	150,000	–	–	150,000
April 2020 Warrants	\$ 2.21	10/2/2025	–	1,713,064	(428,266)	–	1,284,798
April 2020 Placement Agent Warrants	\$ 2.9188	3/31/2025	–	128,480	–	–	128,480
			<u>480,035</u>	<u>5,509,746</u>	<u>(2,408,133)</u>	<u>(2,364)</u>	<u>3,579,284</u>

There were no warrants exercised during the three months ended September 30, 2020 and 2019.

During the nine months ended September 30, 2020, the Company received net proceeds of \$3,856,000 from the exercise of warrants. During the nine months ended September 30, 2019, the Company received net proceeds of \$60,000 from the exercise of warrants.

Of the warrants exercised during the nine months ended September 30, 2020, 428,266 of the Company's April 2020 Warrants were exercised via a cashless exercise transaction and as a result a total of 225,796 shares of common stock were issued. There were no cashless exercises of warrants in the three months ended September 30, 2020 or the three and nine months ended September 30, 2019.

8. Net Loss per Share

The following table sets forth the potential common shares excluded from the calculation of net loss per share because their inclusion would be anti-dilutive:

	September 30,	
	2020	2019
Options to purchase common stock	2,637	2,650
Restricted stock units	10,731	9,404
Warrants to purchase common stock	3,579,284	487,569
Total	<u>3,592,652</u>	<u>499,623</u>

9. Stock-based Compensation

Restricted Stock Units

Restricted stock units (“RSUs”) are issued under the Company’s 2012 Long-Term Incentive Plan or as inducement grants issued outside of the plan to new employees. RSUs are generally subject to graded vesting and the satisfaction of service requirements. Upon vesting, each outstanding RSU will be exchanged for one share of the Company’s common stock. Employee RSU recipients may elect to net share settle upon vesting, in which case the Company pays the employee’s income taxes due upon vesting and withholds a number of shares of equal value. The fair value of the RSUs awarded are based upon the Company’s closing stock price at the grant date and are expensed over the requisite service period.

The following table summarizes the activity of the Company’s RSUs for the nine months ended September 30, 2020:

	Number of Shares	Weighted- Average Grant Date Fair Value
Unvested units at December 31, 2019	14,945	\$ 20.50
Granted	–	–
Vested	(3,782)	24.07
Forfeited	(432)	14.69
Unvested units at September 30, 2020	<u>10,731</u>	<u>\$ 19.47</u>

Stock-based compensation expense related to RSUs for the three months ended September 30, 2020 and 2019 was \$21,000 and \$31,000, respectively. Stock-based compensation expense related to RSUs for the nine months ended September 30, 2020 and 2019 was \$69,000 and \$110,000, respectively.

Stock Options

The Company uses the Black-Scholes option-pricing model to determine the fair value of all its option grants. The risk-free interest rate used for each grant is based upon the yield on zero-coupon U.S. Treasury securities with a term similar to the expected life of the related option. The Company’s expected stock price volatility assumption is based upon the Company’s own implied volatility. The expected life assumption for option grants is based upon the simplified method provided for under ASC 718. The dividend yield assumption is based upon the fact that the Company has never paid cash dividends and presently has no intention of paying cash dividends.

The following table summarizes the activity of the Company’s stock options for the nine months ended September 30, 2020:

	Number of Shares	Weighted- Average Exercise Price Per Share	Aggregate Intrinsic Value
Balance at December 31, 2019	2,659	\$ 3,298.90	
Granted	–	–	
Exercised	–	–	
Cancelled	(22)	10,484.90	
Balance at September 30, 2020	<u>2,637</u>	<u>\$ 3,252.04</u>	\$ –
Exercisable at September 30, 2020	<u>1,842</u>	<u>\$ 4,607.81</u>	<u>\$ –</u>

Stock-based compensation expense related to stock options for the three months ended September 30, 2020 and 2019 was \$16,000 and \$16,000, respectively. Stock-based compensation expense related to stock options for the nine months ended September 30, 2020 and 2019 was \$41,000 and \$53,000, respectively.

Restricted Stock

On August 31, 2018, and through subsequent amendments on December 19, 2018 and February 14, 2019, Geert Cauwenbergh, Dr. Med. Sc., the Company's former Chief Executive Officer, elected the right to receive, in lieu of cash, for the period from September 15, 2018 to February 28, 2019, up to 50% of his base salary and cash bonuses, if any, (collectively, the "**Compensation**") payable in the form of unvested, restricted shares of the Company's common stock. Such restricted shares were received in the form of a series of grants made on each Company payroll date in lieu of cash payment of the Compensation. All shares issued in lieu of Compensation vested in full on June 1, 2019.

The fair value of the restricted stock was based on the Company's closing stock price on the date of grant and was expensed over the vesting period. During the nine months ended September 30, 2019, the Company granted 4,419 shares of restricted stock in lieu of Compensation to Dr. Cauwenbergh and recorded \$106,000 in stock-based compensation related to the restricted stock.

Compensation Expense Related to Equity Awards

The following table sets forth total stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019, in thousands:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 6	\$ 6	\$ 17	\$ 25
General and administrative	31	41	93	244
Total stock-based compensation	\$ 37	\$ 47	\$ 110	\$ 269

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In this document, "we," "our," "ours," "us," "Phio" and the "Company" refers to Phio Pharmaceuticals Corp. and our subsidiary, MirImmune, LLC and the ongoing business operations of Phio Pharmaceuticals Corp. and MirImmune, LLC, whether conducted through Phio Pharmaceuticals Corp. or MirImmune, LLC.

This management's discussion and analysis of financial condition as of September 30, 2020 and results of operations for the three and nine months ended September 30, 2020 and 2019 should be read in conjunction with the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission (the "SEC") on March 26, 2020.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as "intends," "believes," "anticipates," "indicates," "plans," "expects," "suggests," "may," "would," "should," "potential," "designed to," "will," "ongoing," "estimate," "forecast," "predict," "could" and similar references, although not all forward-looking statements contain these words. Forward-looking statements are neither historical facts nor assurances of future performance. These statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Risks that could cause actual results to vary from expected results expressed in our forward-looking statements include, but are not limited to, the impact to our business and operations by the recent coronavirus outbreak, the development of our product candidates, our ability to execute on business strategies, our ability to develop our product candidates with collaboration partners, the timeline and duration for advancing our product candidates into clinical development, results from our preclinical and clinical activities and our ability to obtain future financing. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements as a result of a number of important factors, including those identified in our Annual Report on Form 10-K for the year ended December 31, 2019 under the heading "Risk Factors" and in other filings the Company periodically makes with the SEC. Therefore, you should not rely on any of these forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q speak as of the date hereof and the Company does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this report.

Overview

Phio Pharmaceuticals Corp. is a biotechnology company developing the next generation of immuno-oncology therapeutics based on our self-delivering RNAi ("INTASYL™") therapeutic platform. Our efforts are focused on silencing tumor-induced suppression of the immune system through our proprietary INTASYL platform with utility in immune cells and the tumor micro-environment. Our goal is to develop powerful INTASYL therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby potentially providing patients a powerful new treatment option that goes beyond current treatment modalities.

Our development efforts are based on our broadly patented INTASYL technology platform. Our INTASYL compounds do not require a delivery vehicle to penetrate into tissues and cells and are designed to "silence" or down-regulate, the expression of a specific gene which is over-expressed in cancer. We believe that our INTASYL platform uniquely positions the Company in the field of immuno-oncology because of this and the following reasons:

- Efficient uptake of INTASYL by target cells obviating the need for facilitated delivery (mechanical or formulation);
- Does not require permanent genetic modification;
- Can target multiple genes (i.e. multiple immunosuppression pathways) in a single therapeutic entity;
- Gene silencing by INTASYL has been shown to have a sustained, or long-term, effect *in vivo*;
- Favorable clinical safety profile of INTASYL with local administration; and
- Can be readily manufactured under current good manufacturing practices.

The self-delivering nature of our compounds makes INTASYL ideally suited for use with adoptive cell transfer (“ACT”) treatments and direct therapeutic use. ACT consists of the infusion of immune cells with antitumor properties, after growing them in a lab to large numbers. These cells can be derived from unmodified (i.e. naturally occurring) immune cells, immune cells isolated from resected tumors, or genetically engineered immune cells that recognize tumor cells.

Regardless of the source of immune cells (ACT or naturally occurring immune cells), in patients with solid tumors, these cells face several hurdles. Multiple inhibitory mechanisms restrain immune cells from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence. Furthermore, the immunosuppressive tumor micro-environment (the “TME”) can pose a formidable barrier to immune cell infiltration and function.

We have developed a product platform based on our INTASYL technology that allows easy, precise, rapid, and selective non-genetically modified programming of ACT cells (*ex vivo*, during manufacturing) and of the TME (*in vivo*, by local application), resulting in reduced immune inhibition and in improved immunotherapy.

Adoptive Cell Transfer

ACT includes a number of different types of immunotherapy treatments. These treatments use immune cells, isolated from patients, donors or retrieved from allogeneic immune cell banks. They are grown in a lab to large numbers, followed by administering them to the body to fight the cancer cells. Sometimes, immune cells that naturally recognize a tumor are used, while other times immune cells are modified or “genetically engineered” to make them recognize and kill the cancer cells. There are several types of ACT, including: a.) non-engineered cell therapy in which immune cells are grown from the patient’s tumor or blood, such as tumor infiltrating lymphocytes (“TILs”), or from donor blood or tissue such as natural killer (“NK”) cells, dendritic cells (“DC”) and macrophages, and b.) genetically engineered immune cells that are genetically modified to recognize specific tumor proteins and to remain in an activated state (such as T cell receptor technology (“TCRs”), chimeric antigen receptor (“CAR”) T cells, or CAR-NK cells).

In ACT, such immune cells are then expanded and modified before being returned and used to treat the patient. Multiple inhibitory mechanisms restrain immune cells used in ACT from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence, and other barriers to immune cell infiltration and function mainly in solid tumors. We believe our INTASYL compounds are ideally suited to be used in combination with ACT, in order to make these immune cells more effective without the need for additional complicated manufacturing steps and/or genetic engineering.

Our approach builds on well-established methodologies of ACT and involves the treatment of immune cells with our INTASYL compounds *ex vivo* while they are grown in the lab and before administering them to the patient. Because our INTASYL compounds do not require a delivery vehicle to penetrate into the cells, we are able to enhance the function of these cells by merely adding our INTASYL compounds during the expansion process and without the need for genetic engineering and without additional needed complex manufacturing steps. By adding INTASYL to the cell culture media used during the cell expansion, we can reduce or eliminate the expression of genes that make the immune cells less effective. For example, with our INTASYL compounds, we can reduce the expression of immunosuppressive proteins by the therapeutic immune cells, potentially enabling them to overcome tumor resistance mechanisms and thus improving their ability to destroy the tumor cells. In various types of immune cells tested to date, INTASYL treatment results in potent silencing with close to 100% transfection efficiency and while maintaining nearly full cell viability. After expanding these cells and enhancing them with INTASYL *ex vivo*, they are returned to the patient for treatment.

Our lead product candidate and most advanced program being developed in ACT is PH-762, an INTASYL compound that targets the checkpoint protein PD-1. Checkpoint proteins, such as PD-1, normally act as a type of “off switch” that prevents T cells from attacking certain cells, such as cancer cells, in the body. Our T cells are immune cells that protect the body from cancer cells and infections.

Data developed by Phio and with collaborators has shown that PH-762 silences PD-1 checkpoint expression, thereby removing the “off switch” and resulting in enhanced T cell activation and tumor cytotoxicity. Experimental data shows that PH-762 can silence the expression of PD-1 in target human T cells in a potent and durable manner, and can increase function of patient derived TILs for use in ACT, showing that PH-762 is suitable for use both in ACT and as a standalone therapeutic through intra-tumoral injection. This supports the application of INTASYL technology in immunotherapy of cancer.

Our second ACT product candidate PH-894, an INTASYL compound that targets BRD4, is a regulator of gene expression impacting cell differentiation. In previous studies, PH-894 has been shown to improve T cell function and persistence by differentiating T cells into a more active state (stem-cell like memory phenotype). Data, completed in partnership with the Karolinska Institutet, demonstrated that the application of PH-894, was shown to silence BRD4 in human T cells during expansion for ACT, which has the potential to confer superior anti-tumor activity, for example by improving T cell persistence. With this data, we expanded our collaboration with the Karolinska Institutet to build upon these findings and develop INTASYL compounds for additional targets and cell types toward clinical application in areas of the Karolinska Institutet's ongoing clinical research.

We are also developing our INTASYL compound PH-804 for use in ACT. PH-804 targets the suppressive immune receptor TIGIT, which is a checkpoint protein present on T cells and NK cells. To date, we have shown that PH-804 can silence the expression of TIGIT in NK cells and T cells, overcoming their "off switch" and the cells becoming "weaponized" to kill cancer cells.

In March 2020, we entered into a collaboration and option agreement with Medigene AG and the Helmholtz Zentrum München ("HMGU"). This three-way collaboration expands upon our outstanding research agreement with HMGU to design and develop novel candidates for the use of INTASYL compounds in ACT to enhance immune cell function. Under the agreement, Medigene AG will contribute expertise regarding clinical development, as well as proprietary research material and has the option to an exclusive license for the clinical and/or commercial development of certain INTASYL immune cell enhancers.

Tumor Micro-Environment

The TME is the environment that surrounds and feeds a tumor, including normal cells, blood vessels, immune cells, and the extracellular matrix. The TME is an immunosuppressive environment that inhibits the immune system's natural ability to recognize and destroy tumor cells by negatively impacting how immunosuppressive cells are being attracted and activated. Reprogramming different components of the TME may overcome resistance to immunotherapy. Such reprogramming of the TME by INTASYL compounds through direct local administration into the tumor, could potentially become an important form of therapy. The Company has previously shown in a clinical setting that our INTASYL compounds are safe and well-tolerated following local administration, therefore we believe that our INTASYL technology can not only be used with ACT, but can also be used as an independent therapeutic platform.

We have pipeline programs in place for the development of INTASYL compounds for direct administration into the tumor, including the use of PH-762, PH-804 and PH-894 for *in situ* transfection and activation of immune cells in the TME.

Data presented in January 2020 from *in vivo* studies performed by the Company showed that intra-tumoral injection of a mouse version of PH-804 reduced the tumor growth in colorectal carcinoma tumor bearing mice, which was shown to inhibit tumor growth and was correlated with the silencing of TIGIT mRNA expression and an increase in cytotoxic effector T cells in the TME.

Building on the animal data with PH-804, the Company conducted several animal studies with a mouse version of PH-762 and with PH-894 in a validated mouse model of hepatocellular carcinoma. These studies showed that local administration of the mouse version of PH-762 or PH-894 through intra-tumoral injection resulted in potent anti-tumoral effects. The treated animals showed a complete and statistically significant inhibition of tumor growth, whereas placebo treated animals displayed exponential tumor growth. The combined PH-804, PH-762, and PH-894 data further shows that INTASYL compounds can trigger associated changes in the TME such as an increase of TILs, including CD8+ T cells responsible for tumor cell killing, and an increase of activation markers on these cells. These preclinical findings demonstrate that direct injection of INTASYL compounds can successfully infiltrate solid tumors and impact the TME by activating the immune response in animal models of solid tumors resulting in reduced tumor growth. This is one of the key challenges for many other immunotherapy platforms to be able to achieve an adequate therapeutic effect in solid tumors.

We are also investigating other relevant compounds for TME targets, such as PH-790, an INTASYL compound targeting PD-L1. PD-L1 is a protein formed by cancer cells that activate the PD-1 “off switch” on immune cells. Our approach with PH-790 is to block the formation of the PD-L1 protein, which may prevent cancer cells from inactivating T cells and attack the cancer, and will be evaluated alongside PH-762. Previously, a series of preclinical *in vivo* studies in tumor models showed dose-dependent attenuated tumor growth for the INTASYL compounds compared to control groups. Recent data presented at the 35th Annual Meeting of Society for Immunotherapy of Cancer in November 2020 demonstrated that the antitumoral efficacy of our individual pipeline products, PH-762, PH-790 and PH-804, can be further improved by combining them in a single drug treatment. This data showed that the combination of our INTASYL compounds inhibited tumor growth without having a negative impact on the tolerability of the treatment.

Based on our positive preclinical data, the Company is preparing for its first in-human clinical study with PH-762 using intra-tumoral administration for patients with advanced melanoma. The rationale for the study and its design were recently presented at a key opinion leader event held by the Company in June 2020 with Dr. Caroline Robert of the Gustave Roussy Cancer Center in Paris, France who will be our lead principal investigator for the trial.

Impact of COVID-19 on our Business

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States. In March 2020, the World Health Organization (the “**WHO**”) declared the outbreak a pandemic.

Health and Safety

From the first signs of the outbreak, we have taken proactive measures intended to protect the health and safety of our employees. We have implemented safety measures following the guidance provided by the WHO and the Centers for Disease Control (the “**CDC**”) such as working remotely for employee personnel who do not need to be physically present in our premises, social distancing protocols, suspending travel, and extensively and frequently disinfecting our workspaces. We expect to continue following these safety measures and may take further actions as we require, as government authorities require or recommend, or as we determine to be in the best interests of our employees, partners and suppliers.

Operations

The coronavirus pandemic is affecting the United States and global economies and as a result, government authorities have implemented restrictions and limited certain operations, such as limits on the number of people at a gathering, travel restrictions and stay-at-home orders, to try and slow the spread of coronavirus. Our office and lab space are located in one facility in Marlborough, Massachusetts and on March 23, 2020, Massachusetts ordered most physical business workplaces closed, mandating work-from-home arrangements, where feasible, in response to the coronavirus pandemic. The order excluded businesses that provide certain essential services, which included companies operating in the biotechnology and life sciences industry. As a result, our facility remained operational with employee personnel who did not need to be physically present in our premises working remotely during that time.

On May 18, 2020, Massachusetts commenced its four phased approach and re-opening plan of the economy, which allows for the gradual re-opening of each sector, industry and business in line with state mandated workplace safety standards and sector-specific protocols and best practices. The Company’s facilities remain operational and are operating in accordance with Massachusetts’ mandated requirements, as well as in accordance with the federal government, WHO, CDC and other governmental authority guidelines. Employee personnel who do not need to be physically present on our premises are continuing to work remotely, but have the ability to be on site as required. Safety measures are in place for the health and safety of our employees, including formal policies related to health checks, wearing a face mask, staggered scheduling and socially distancing, in line with the guidelines provided by government authorities. While these measures may be modified or extended, we expect that our activities, including our internal research and development functions, will continue to remain largely operational.

We have experienced limited absenteeism from our employees and we do not currently expect that our operations will be significantly impacted by employee absenteeism.

While we believe the impact to our internal operations has been minimal thus far, current and future restrictions may further impact our operations and may slow or diminish our research and development activities.

Supply and Services

If the measures to contain the outbreak continue or are extended, it may affect our operations and those of third parties on which we rely, including causing disruptions in the supplies we order, outsourced development services for our product candidates and the conduct of current and planned preclinical and clinical studies. Presumably as a result of the coronavirus pandemic, we have begun to see some of our third-party suppliers and service providers on which we rely becoming impacted. If the impact on their operations continue or extend, it may affect our operations. We previously had been able to engage with third-party service providers in areas with limited or no impact (e.g. countries with limited or no restrictions), but with the global spread of the virus and associated restrictions, this has been no longer possible. Our service providers, for example those performing required preclinical research studies, are now facing impacts to their operations, including restrictions on the availability of critical materials that are needed for this type of research. Without a significant and sustained improvement of the current situation, we may experience significant impacts to certain of our development activities outsourced to third-party service providers, however, the ultimate impact on our third-party service providers is highly uncertain and subject to change. If the measures to contain the outbreak are extended or further expanded, it could reduce or delay the availability of supplies and services that we purchase and outsource. This may in turn slow or delay our preclinical and clinical research and development activities, and/or result in higher costs.

We anticipate a continued decline in the commencement of new clinical trials, at least in the short-term, as many Institutional Review Boards (the “**IRB**”) are currently focused on reviewing and approving clinical trial protocols related to COVID-19. Additionally, due to the implementation of restrictive measures such as stay-at-home orders by government authorities in the United States and global economies to try and contain the spread of coronavirus, we anticipate a continued negative impacts, at least in the short-term, in the enrollment and participation of patients in clinical trials outside of those related to COVID-19.

The required studies and steps needed to initiate clinical trials with PH-762 in the 2021 timeframe are continuing and ongoing, however, the ultimate impact of the coronavirus pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business and preclinical and clinical trial activities.

Liquidity and Capital Resources

While we believe that the coronavirus pandemic has not had a significant impact on our financial condition and results of operations at this time, the extent to which the coronavirus pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus pandemic and the actions to contain the coronavirus or treat its impact, among others. We believe that our current cash on hand should be sufficient to fund our operations for at least the next twelve months from the date of the release of these financial statements, although the pandemic has created uncertainty around our ability to access capital markets to provide necessary working capital to fund our long term operations.

In light of this uncertainty around our ability to access additional working capital, on May 11, 2020, the Company received loan proceeds in the amount of \$231,252 from Bank of America, N.A., as lender, pursuant to the PPP under the CARES Act. The PPP loan matures on May 11, 2022 and bears interest at a rate of 1% per year. The loan may be forgiven if used for eligible purposes, including payroll, benefits, rent and utilities. Monthly principal, interest and other fee payments are deferred until the date on which the determination of PPP loan forgiveness is remitted to the lender, or ten (10) months after the end of the borrower’s loan forgiveness covered period. The Company carefully assessed the requirements for application under the PPP and believes that the loan is necessary to support its operations. The Company intends to apply for loan forgiveness and while the Company has used the PPP loan proceeds for the eligible purposes allowed, the Company cannot guarantee that the loan will be forgiven.

In connection with and in addition to the PPP loan, we have taken other proactive steps to control costs in response to the coronavirus pandemic and these actions include the reduction of the salaries of our senior management team by 10% through the remainder of 2020. We believe these savings will help mitigate the financial impact of the coronavirus pandemic.

Additionally, while the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to complete our preclinical and planned clinical studies on a timely basis, or at all. There may be developments outside of our control that require us to adjust our operating plans and given the nature of the situation, cannot reasonably estimate the impact of the coronavirus on our financial condition, results of operations or cash flows in the future.

In addition, risk factors identified in our Annual Report on Form 10-K for the year ended December 31, 2019 under the heading “*Risk Factors*,” which was filed with the SEC on March 26, 2020, should be read in conjunction with Part II—Item 1A, “*Risk Factors*,” included herein for updates to our risk factors regarding risks associated with the COVID-19 pandemic.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based upon our condensed 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 related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and base our estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions and could have a material impact on our reported results. There have been no significant changes to our critical accounting policies since the beginning of this fiscal year. Our critical accounting policies are described in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our Annual Report on Form 10-K for the year ended December 31, 2019, which we filed with the SEC on March 26, 2020.

Results of Operations

The following data summarizes the results of our operations for the periods indicated, in thousands:

Description	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Dollar Change	2020	2019	Dollar Change
Revenues	\$ —	\$ —	\$ —	\$ —	\$ 21	\$ (21)
Operating expenses	2,306	2,113	193	6,331	6,339	(8)
Operating loss	(2,306)	(2,113)	(193)	(6,331)	(6,318)	(13)
Net loss	(2,309)	(2,094)	(215)	(6,332)	(6,248)	(84)

Comparison of the Three and Nine Months Ended September 30, 2020 and 2019

Operating Expenses

The following table summarizes our total operating expenses, for the periods indicated, in thousands:

Description	Three Months Ended September 30,		Dollar Change	Nine Months Ended September 30,		Dollar Change
	2020	2019		2020	2019	
Research and development	\$ 1,256	\$ 1,042	\$ 214	\$ 3,253	\$ 3,277	\$ (24)
General and administrative	1,050	1,071	(21)	3,078	3,062	16
Total operating expenses	<u>\$ 2,306</u>	<u>\$ 2,113</u>	<u>\$ 193</u>	<u>\$ 6,331</u>	<u>\$ 6,339</u>	<u>\$ (8)</u>

Research and Development Expenses

Research and development expenses relate to compensation and benefits for research and development personnel, facility-related expenses, supplies, external services, costs to acquire technology licenses, expenses associated with preclinical and clinical development activities and other operating costs.

Research and development expenses for the three months ended September 30, 2020 increased 21% as compared with the three months ended September 30, 2019, primarily due to an increase in the use of third-party service providers to conduct preclinical research studies to support the development of the Company's pipeline programs as compared to the prior year period offset by a decrease in the use of an outside interim temporary labor consultant in the prior year period.

Research and development expenses for the nine months ended September 30, 2020 decreased 1% as compared with the nine months ended September 30, 2019, primarily due to decreases in lab supply purchases, in the use of an outside interim temporary labor consultant and decreased patent-related expenses as compared to the prior year period offset by increases in the use of third-party service providers to conduct preclinical research studies to support the development of the Company's pipeline programs.

General and Administrative Expenses

General and administrative expenses relate to compensation and benefits for general and administrative personnel, facility-related expenses, professional fees for legal, audit, tax and consulting services, as well as other general corporate expenses.

General and administrative expenses for the three months ended September 30, 2020 decreased 2% as compared with the three months ended September 30, 2019, primarily due to a decrease in recruiting fees to support employee hiring activities as compared to the same period in the prior year.

General and administrative expenses for the nine months ended September 30, 2020 increased 1% as compared with the nine months ended September 30, 2019, primarily due to increases in the Company's D&O insurance premiums and the use of business development consultants offset by a decrease in recruiting fees to support employee hiring activities as compared to the same period in the prior year.

Liquidity and Capital Resources

On August 8, 2017, the Company entered into a purchase agreement (the “**2017 Purchase Agreement**”) and a registration rights agreement with Lincoln Park Capital Fund, LLC (“**LPC**”), pursuant to which the Company had the right to sell to LPC up to \$15,000,000 in shares of the Company’s common stock, subject to certain limitations and conditions set forth therein, over the 30-month term of the 2017 Purchase Agreement. The 2017 Purchase Agreement expired on April 1, 2020 and a total of 9,000 shares of common stock were sold to LPC for net proceeds of \$1,602,000 under the 2017 Purchase Agreement.

On August 7, 2019, the Company entered into a purchase agreement (the “**2019 Purchase Agreement**”) and a registration rights agreement with LPC, pursuant to which the Company has the right to sell to LPC up to \$10,000,000 in shares of the Company’s common stock over the 30-month term of the 2019 Purchase Agreement, subject to certain limitations and conditions. The 2019 Purchase Agreement initially limits the Company’s issuance of shares of common stock to LPC to 19.99% of the Company’s shares outstanding on the date of the 2019 Purchase Agreement unless stockholder approval is obtained to issue more than such amount or the average price of all sales under the 2019 Purchase Agreement exceed certain amounts as set forth in the 2019 Purchase Agreement. To date, no shares of common stock have been sold to LPC under the 2019 Purchase Agreement.

On February 6, 2020, the Company closed its February 2020 Registered Offering. Net proceeds to the Company from the February 2020 Registered Offering were \$1,467,000 after deducting placement agent fees and offering expenses paid by the Company.

On February 13, 2020, the Company closed its February 2020 Underwritten Offering. Net proceeds from the February 2020 Underwritten Offering were \$7,093,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company.

On April 2, 2020, the Company closed its April 2020 Offering. Net proceeds to the Company from the April 2020 Offering were \$3,527,000 after deducting placement agent fees and offering expenses paid by the Company.

We had cash of \$16,868,000 as of September 30, 2020, compared with \$6,934,000 as of December 31, 2019. We have reported recurring losses from operations since inception and expect that we will continue to have negative cash flows from our operations for the foreseeable future. Historically, the Company’s primary source of funding has been the sale of its securities. In the future, we will be dependent on obtaining funding from third parties, such as proceeds from the issuance of debt, sale of equity, or strategic opportunities, in order to maintain our operations. There is no guarantee that debt, additional equity or other funding will be available to us on acceptable terms, or at all. Moreover, the global coronavirus pandemic has led to significant uncertainty and increased volatility in the capital markets. If these conditions in the capital markets continue for an extended period of time it may impact our ability to raise capital. If we fail to obtain additional funding when needed, we would be forced to scale back or terminate our operations or to seek to merge with or to be acquired by another company. We believe that our existing cash should be sufficient to fund operations for at least the next twelve months from the date of the release of these financial statements.

The following table summarizes our cash flows for the periods indicated, in thousands:

	Nine Months Ended September 30,	
	2020	2019
Net cash used in operating activities	\$ (6,179)	\$ (6,099)
Net cash used in investing activities	(18)	(77)
Net cash provided by financing activities	16,131	6
Net increase (decrease) in cash and restricted cash	<u>\$ 9,934</u>	<u>\$ (6,170)</u>

Net Cash Flow from Operating Activities

Net cash used in operating activities was \$6,179,000 for the nine months ended September 30, 2020, as compared with \$6,099,000 for the nine months ended September 30, 2019. The increase in cash used in operating activities was primarily due to an increase in net loss as compared to the same period in the prior year.

Net Cash Flow from Investing Activities

Net cash used in investing activities was \$18,000 for the nine months ended September 30, 2020, as compared with \$77,000 for the nine months ended September 30, 2019. The decrease in net cash flows from investing activities was primarily related to the amount of laboratory and computer equipment purchases year over year.

Net Cash Flow from Financing Activities

Net cash provided by financing activities was \$16,131,000 for the nine months ended September 30, 2020, as compared with \$6,000 for the nine months ended September 30, 2019. The increase in net cash flows from financing activities was primarily due to net proceeds received by the Company from the issuance of securities and warrant exercises during the nine months ended September 30, 2020 as compared to the same period in the prior year.

Off-Balance Sheet Arrangements

In connection with certain license agreements, we are required to indemnify the licensor for certain damages arising in connection with the intellectual property rights licensed under the agreement. In addition, we are a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate us to indemnify the other parties to such agreements upon the occurrence of certain events. These indemnification obligations are considered off-balance sheet arrangements in accordance with ASC Topic 460, “*Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.*” To date, we have not encountered material costs as a result of such obligations and have not accrued any liabilities related to such obligations in our financial statements. See Note 7 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on March 26, 2020, for further discussion of these indemnification agreements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide this information.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (who is also acting as our principal financial officer) and our Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), as of the end of the period covered by this report to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of the end of the period covered by this report, management, with the participation of our Chief Executive Officer (who is also acting as our principal financial officer) and our Principal Accounting Officer, concluded that our disclosure controls and procedures were effective as of such date.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the nine months ended September 30, 2020 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

From time to time, the Company may become a party to various legal proceedings and complaints arising in the ordinary course of business. There are none deemed to be material at this time.

ITEM 1A. RISK FACTORS

Please carefully consider the information set forth in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 26, 2020. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including these risks.

Risks Relating to Our Business and Industry

Our business and operations may be materially and adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus was reported to have surfaced in China and has since spread to other parts of the world. In March 2020, the WHO declared the outbreak a pandemic. The coronavirus pandemic is affecting the United States and global economies and as a result, government authorities have implemented restrictions and limited certain operations, such as limits on the number of people at a gathering, travel restrictions and stay-at-home orders, to try and slow the spread of coronavirus. These mandates generally excluded businesses that provide certain essential services, such as companies operating in the biotechnology and life sciences industry. As a result, our facility remained operational with employee personnel who did not need to be physically present in our premises working remotely during that time. In May 2020, Massachusetts, along with other states in the United States, began its re-opening of the economy, allowing for the gradual opening of businesses in line with state mandated workplace safety standards, specific protocols and best practices. The Company’s facilities remain operational and are operating in accordance with federal and state governmental authority guidelines. Employee personnel who do not need to be physically present on our premises are continuing to work remotely, but have the ability to be on site as required. While the majority of these mandates have specific end dates, they may be modified or extended and as a result there is uncertainty regarding the length of time that such measures will be in place. We believe the impact to our internal operations has not been material thus far, however, current and future restrictions may further impact our operations and may slow or diminish our research and development activities.

In response to the coronavirus pandemic, we have taken proactive measures to protect the health and safety of our employees. We have implemented safety measures following the guidance provided by the WHO and the CDC such as working remotely for employee personnel who do not need to be physically present in our premises, social distancing protocols, suspending travel and extensively and frequently disinfecting our workspaces. We have experienced limited absenteeism from our employees, but absenteeism may increase in the future, employees working remotely may experience limited productivity due to the resources available at home or we may not be able to maintain the necessary information technology infrastructure to adequately support our employees working remotely. Further, our increased reliance on remote access to our information systems increases our exposure to potential cybersecurity breaches. We expect to continue following these safety measures and may take further actions as we require, as government authorities require or recommend, or as we determine to be in the best interests of our employees, partners and suppliers.

The extent to which the coronavirus pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. We do not yet know the full extent of potential delays or the impact on our business, financial condition, or our preclinical and clinical trial activities. There may be developments outside of our control that require us to adjust our operating plans and given the nature of the situation, cannot reasonably estimate the impact of the coronavirus pandemic on our financial condition, results of operations or cash flows in the future.

We rely upon third parties for the supply of our product candidates, other resources and the conduct of our preclinical and clinical activities.

If the measures to contain the coronavirus outbreak continue or are extended, it may adversely affect our operations and those of third parties on which we rely, including causing disruptions in the supplies we order, outsourced development services for our product candidates and the conduct of current and planned preclinical and clinical studies. Presumably as a result of the pandemic, we have begun to see some of our third-party suppliers and service providers on which we rely becoming impacted. If the impact on their operations continue or extend, it may affect our operations. We previously had been able to engage with third-party service providers in areas with limited or no impact (e.g. countries with limited or no restrictions), but with the global spread of the virus and associated restrictions, this has been no longer possible. Our service providers, for example those performing required preclinical research studies, are now facing impacts to their operations, including restrictions on the availability of critical materials that are needed for this type of research. Without a significant and sustained improvement of the current situation, we may experience significant impacts to certain of our development activities outsourced to third-party service providers, however, the ultimate impact on our third-party service providers is highly uncertain and subject to change. If the measures to contain the outbreak are extended or further expanded, it could reduce or delay the availability of supplies and services that we purchase and outsource or result in closures of businesses that we work with. This may in turn slow or delay our preclinical and clinical research and development activities, and/or result in higher costs. The ultimate impact of the coronavirus pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business and preclinical and clinical trial activities.

Anticipated declines in the commencement of and enrollment of clinical trials, at least in the short-term, may cause delays in any future planned clinical trials for our product candidates and may adversely affect our business.

The first stage of the Federal Drug Administration (the “FDA”) approval process for a new biologic or drug involves the submission of an investigational new drug application, which includes the clinical protocol along with the approval of the IRB at the institutions participating in the trials prior to commencement of human clinical trials. We anticipate a continued decline in the commencement of new clinical trials, at least in the short-term, as regulatory authorities and IRBs are currently focused primarily on reviewing and approving clinical trial protocols related to COVID-19. Additionally, due to the implementation of restrictive measures such as stay-at-home orders by government authorities in the United States and global economies to try and contain the spread of coronavirus, we anticipate a continued negative impacts, at least in the short-term, in the enrollment and participation of patients in clinical trials outside of those related to COVID-19. The impact on clinical trial operations may be temporarily delayed or regulatory clearances and approvals paused. Therefore, our planned preclinical and clinical activities, including the commencement of clinical trials for our drug candidates, may be temporarily delayed or paused as a result, which may, in turn, impact our expected development milestones.

The required studies and steps needed to initiate clinical trials with PH-762 in the 2021 timeframe are continuing and ongoing, however, we are reliant on third-party service providers for certain of our preclinical and clinical activities who may be negatively impacted by the implementation of restrictive measures by governmental authorities which are difficult to assess or predict at this time. In turn, our PH-762 programs may be delayed as a result. The ultimate impact of the coronavirus pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business and preclinical and clinical trial activities and these effects could have a material impact on the Company’s liquidity, capital resources, operations and business and those of the third parties on which we rely.

We may not be able to obtain sufficient financing and may not be able to develop our product candidates.

We believe that our current cash on hand should be sufficient to fund our operations for at least the next twelve months from the date of the release of these financial statements. However, we have generated significant losses to date, have not generated any product revenue and may not generate product revenue in the foreseeable future, or ever. We expect to incur significant operating losses as we advance our product candidates through drug development and the regulatory process. In the future, we may need to issue equity or incur debt in order to fund our planned expenditures, as well as to make acquisitions and other investments. We cannot assure you that equity or debt financing will be available to us on acceptable terms, or at all. Were we able to access capital, there may be risks associated with the terms of such capital, including dilution (in the case of equity offerings), risks of repayment and default (in the case of debt) and reputational risks (in the case of obtaining government assistance, such as through a PPP loan). If we cannot, or are limited in the ability to, issue equity, incur debt or enter into strategic collaborations, we may be unable to fund the discovery and development of our product candidates, address gaps in our product offerings or improve our technology.

Moreover, the global coronavirus pandemic has led to significant uncertainty and increased volatility in the capital markets. Additionally, while the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to complete our preclinical and planned clinical studies on a timely basis, or at all. The ultimate impact of coronavirus is highly uncertain and subject to change. While we anticipate that we will experience an impact to our research and development activities, we do not yet know the full extent of potential delays or the impact on our business, financial condition, or our preclinical and clinical trial activities. There may be developments outside of our control that require us to adjust our operating plans and given the nature of the situation, cannot reasonably estimate the impact of the coronavirus on our financial condition, results of operations or cash flows in the future.

We anticipate that we will need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, which may include but is not limited to the following:

- To conduct research and development to successfully develop our technologies;
- To obtain regulatory approval for our products;
- To file and prosecute patent applications and to defend and assess patents to protect our technologies;
- To retain qualified employees, particularly in light of intense competition for qualified personnel;
- To manufacture products ourselves or through third parties;
- To market our products, either through building our own sales and distribution capabilities or relying on third parties; and
- To acquire new technologies, licenses or products.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings: any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, any action asserting a claim against the Company arising pursuant to any provision of the Delaware General Corporation Law or the Company's certificate of incorporation or bylaws, or any action asserting a claim against the Company governed by the internal affairs doctrine. Despite the fact that our certificate of incorporation provides for this exclusive forum provision to be applicable to the fullest extent permitted by applicable law, Section 27 of the Securities and Exchange Act of 1934, as amended (the "**Exchange Act**"), creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and Section 22 of the Securities Act of 1933, as amended (the "**Securities Act**"), creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, this provision of our certificate of incorporation would not apply to claims brought to enforce a duty or liability created by the Securities Act, Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

ITEM 6. EXHIBITS**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>	<u>Incorporated by Reference Herein</u>	
		<u>Form</u>	<u>Date</u>
31.1	Sarbanes-Oxley Act Section 302 Certification of Principal Executive Officer and Principal Financial Officer. *		
32.1	Sarbanes-Oxley Act Section 906 Certification of Principal Executive Officer and Principal Financial Officer. *		
101	The following financial information from the Quarterly Report on Form 10-Q of Phio Pharmaceuticals Corp. for the quarter ended September 30, 2020, formatted in XBRL (eXtensible Business Reporting Language): (1) Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019; (2) Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2020 and 2019; (3) Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2020 and 2019; (4) Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2020 and 2019; and (5) Notes to Condensed Consolidated Financial Statements (Unaudited).*		

* Filed herewith.

SIGNATURES

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

Phio Pharmaceuticals Corp.

By: /s/ Gerrit Dispersyn
Gerrit Dispersyn, Dr. Med. Sc.
President and Chief Executive Officer

Date: November 10, 2020

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

I, Gerrit Dispersyn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Phio Pharmaceuticals Corp.;
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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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, 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 my 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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 controls over financial reporting.

Dated: November 10, 2020

/s/ Gerrit Dispersyn

Gerrit Dispersyn, Dr. Med. Sc.
President and Chief Executive Officer
(as Principal Executive and Financial Officer)

**CERTIFICATION 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 on Form 10-Q of Phio Pharmaceuticals Corp. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his 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. The information contained in the Report fairly presents, in all material respects, the Company's financial condition and result of operations.

/s/ Gerrit Dispersyn_____

Gerrit Dispersyn, Dr. Med. Sc.
President and Chief Executive Officer
(as Principal Executive and Financial Officer)

November 10, 2020