

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

FORM 10-Q

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

For the quarterly period ended September 30, 2022

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 or other jurisdiction of incorporation or organization)

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, including area code: (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 period that the registrant was required to submit such files). Yes No

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

Large accelerated filer	<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 13(a) of the Exchange 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 4, 2022, Phio Pharmaceuticals Corp. had 13,667,973 shares of common stock, \$0.0001 par value, outstanding.

PHIO PHARMACEUTICALS CORP.
FORM 10-Q — QUARTER ENDED SEPTEMBER 30, 2022

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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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash	\$ 14,484	\$ 24,057
Restricted cash	50	50
Prepaid expenses	843	620
Total current assets	15,377	24,727
Right of use asset, net	192	283
Property and equipment, net	198	133
Other assets	24	27
Total assets	<u>\$ 15,791</u>	<u>\$ 25,170</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 543	\$ 283
Accrued expenses	1,519	2,660
Lease liability	132	125
Total current liabilities	2,194	3,068
Lease liability, net of current portion	70	170
Total liabilities	2,264	3,238
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized	—	—
Common stock, \$0.0001 par value, 100,000,000 shares authorized; 13,667,973 and 13,534,996 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1	1
Additional paid-in capital	139,175	138,831
Accumulated deficit	(125,649)	(116,900)
Total stockholders' equity	13,527	21,932
Total liabilities and stockholders' equity	<u>\$ 15,791</u>	<u>\$ 25,170</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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 2,508	\$ 2,673	\$ 5,398	\$ 6,661
General and administrative	1,063	1,066	3,334	3,400
Total operating expenses	<u>3,571</u>	<u>3,739</u>	<u>8,732</u>	<u>10,061</u>
Operating loss	(3,571)	(3,739)	(8,732)	(10,061)
Total other (expense) income, net	(5)	(3)	(17)	225
Net loss	<u>\$ (3,576)</u>	<u>\$ (3,742)</u>	<u>\$ (8,749)</u>	<u>\$ (9,836)</u>
Net loss per common share:				
Basic	<u>\$ (0.26)</u>	<u>\$ (0.28)</u>	<u>\$ (0.64)</u>	<u>\$ (0.78)</u>
Diluted	<u>\$ (0.26)</u>	<u>\$ (0.28)</u>	<u>\$ (0.64)</u>	<u>\$ (0.78)</u>
Weighted average number of common shares outstanding				
Basic	<u>13,662,857</u>	<u>13,534,560</u>	<u>13,628,931</u>	<u>12,593,569</u>
Diluted	<u>13,662,857</u>	<u>13,534,560</u>	<u>13,628,931</u>	<u>12,593,569</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, 2022**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at December 31, 2021	13,534,996	\$ 1	\$ 138,831	\$ (116,900)	\$ 21,932
Issuance of common stock upon vesting of restricted stock units	155,317	–	–	–	–
Shares withheld for payroll taxes	(31,591)	–	(25)	–	(25)
Stock-based compensation expense	–	–	186	–	186
Net loss	–	–	–	(2,642)	(2,642)
Balance at March 31, 2022	13,658,722	1	138,992	(119,542)	19,451
Stock-based compensation expense	–	–	83	–	83
Net loss	–	–	–	(2,531)	(2,531)
Balance at June 30, 2022	13,658,722	1	139,075	(122,073)	17,003
Issuance of common stock upon vesting of restricted stock units	12,773	–	–	–	–
Shares withheld for payroll taxes	(3,522)	–	(3)	–	(3)
Stock-based compensation expense	–	–	103	–	103
Net loss	–	–	–	(3,576)	(3,576)
Balance at September 30, 2022	<u>13,667,973</u>	<u>\$ 1</u>	<u>\$ 139,175</u>	<u>\$ (125,649)</u>	<u>\$ 13,527</u>

**For the Three and Nine Months
Ended September 30, 2021**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at December 31, 2020	5,780,973	\$ 1	\$ 116,629	\$ (103,613)	\$ 13,017
Issuance of common stock, pre-funded warrants and warrants in connection with private placement, net of offering costs	4,420,863	–	12,669	–	12,669
Issuance of common stock in registered direct offering, net of offering costs	2,246,784	–	6,908	–	6,908
Issuance of common stock upon the exercise of warrants	1,083,321	–	2,146	–	2,146
Issuance of common stock upon vesting of restricted stock units	2,570	–	–	–	–
Shares withheld for payroll taxes	(122)	–	–	–	–
Stock-based compensation expense	–	–	67	–	67
Net loss	–	–	–	(3,407)	(3,407)
Balance at March 31, 2021	13,534,389	1	138,419	(107,020)	31,400
Stock-based compensation expense	–	–	132	–	132
Net loss	–	–	–	(2,687)	(2,687)
Balance at June 30, 2021	13,534,389	1	138,551	(109,707)	28,845
Issuance of common stock upon vesting of restricted stock units	346	–	–	–	–
Shares withheld for payroll taxes	(43)	–	–	–	–
Stock-based compensation expense	–	–	143	–	143
Net loss	–	–	–	(3,742)	(3,742)
Balance at September 30, 2021	<u>13,534,692</u>	<u>\$ 1</u>	<u>\$ 138,694</u>	<u>\$ (113,449)</u>	<u>\$ 25,246</u>

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,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (8,749)	\$ (9,836)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56	55
Non-cash lease expense	91	87
Non-cash stock-based compensation	372	342
Forgiveness of debt	–	(233)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(220)	(10)
Accounts payable	260	(406)
Accrued expenses	(1,141)	711
Lease liability	(93)	(97)
Net cash used in operating activities	(9,424)	(9,387)
Cash flows from investing activities:		
Cash paid for purchase of property and equipment	(121)	(51)
Net cash used in investing activities	(121)	(51)
Cash flows from financing activities:		
Net proceeds from the issuance of common stock and warrants	–	19,577
Net proceeds from the exercise of warrants	–	2,146
Payment of taxes for net share settled restricted stock unit issuances	(28)	–
Net cash (used in) provided by financing activities	(28)	21,723
Net (decrease) increase in cash and restricted cash	(9,573)	12,285
Cash and restricted cash at the beginning of period	24,107	14,294
Cash and restricted cash at the end of period	\$ 14,534	\$ 26,579

The following table provides a reconciliation of cash and restricted cash reported within the Condensed Consolidated Balance Sheets to the totals above:

	September 30,	
	2022	2021
Cash	\$ 14,484	\$ 26,529
Restricted cash	50	50
Total cash and restricted cash	\$ 14,534	\$ 26,579

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

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

1. Organization and Significant Accounting Policies

Nature of Operations

Phio Pharmaceuticals Corp. (“**Phio**,” “**we**,” “**our**” or the “**Company**”) strives to address the biggest challenges in immuno-oncology by working to create new pathways to a cancer-free future for patients. We are developing therapeutics that leverage our INTASYL™ technology to target both tumor and immune cells by regulating genes to strengthen a patient’s immune system while weakening tumor defense mechanisms. With our INTASYL self-delivering RNAi technology, we aim to bring the benefits of RNA therapeutics to the treatment of cancer where other modalities may be ineffective.

The Company continues to respond to and monitor the ongoing coronavirus pandemic. The Company’s corporate headquarters and research facility have seen limited impact and, during the three and nine months ended September 30, 2022, continued to operate with safety measures in place for the health and well-being of its employees, such as working remotely and flexible scheduling, in accordance with guidance from federal, state and local authorities. The Company believes that the coronavirus pandemic has not had a significant impact on its financial condition and results of operations for the three and nine months ended September 30, 2022. However, the extent to which the coronavirus pandemic may materially impact our financial results and operations will depend on a number of factors, including the availability of supplies and services we rely on, the ability to enroll subjects in our clinical trials, the emergence of variant strains of the coronavirus, the development, availability, and public acceptance of effective treatments and vaccines, and the duration of the coronavirus pandemic, which remain difficult to predict and are highly uncertain.

Liquidity

The Company has reported recurring losses from operations since its inception and expects to continue to have negative cash flows from operations for the foreseeable future. Historically, the Company’s primary source of funding has been from sales 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, which may be adversely impacted by the coronavirus pandemic and the ongoing conflict between Russia and Ukraine. There is no guarantee that debt, additional equity or other funding will be available to us on acceptable terms, or at all. 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.

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.

Basis of Presentation

The accompanying financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States (“**GAAP**”). Certain information and footnote disclosures included in the Company’s annual financial statements have been condensed or omitted. Additionally, certain prior year amounts have been reclassified for consistency with the current year presentation. The Company made an adjustment to reflect patent costs within general and administrative operating expenses in the condensed consolidated statements of operations. The reclassification increased general and administrative operating expenses and reduced research and development operating expenses by \$134,000 for the three months ended September 30, 2021 and by \$430,000 for the nine months ended September 30, 2021. This reclassification had no effect on total operating expenses, net loss, net loss per common share and had no impact on the Company’s condensed consolidated balance sheets, statement of stockholders’ equity and statement of cash flows for the prior year period.

The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. These statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s most recent Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the “**SEC**”) on March 22, 2022. 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.

Principles of Consolidation

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

Use 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 as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The areas subject to estimates and judgement include, among others, those related to the fair value of equity awards, accruals for research and development expenses, 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 and the ongoing conflict between Russia and Ukraine. Actual results could differ materially from these estimates.

Summary of Significant Accounting Policies

There have been no material changes to the Company’s significant accounting policies as compared to those disclosed in “Note 2. Summary of Significant Accounting Policies” in our most recent Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 22, 2022.

2. Recent Accounting Pronouncements

In May 2021, the Financial Accounting Standards Board (the “**FASB**”) issued ASU 2021-04, “*Earnings per Share (Topic 260), Debt – Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40)*” (“**ASU 2021-04**”). The amendments in the updates are intended to clarify and reduce diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The amendments in ASU 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted for all entities, including within an interim period. The Company adopted ASU 2021-04 on January 1, 2022. The adoption of this standard had no impact on the Company’s condensed consolidated financial statements.

3. Fair Value of Financial Instruments

The Company follows the provisions of the FASB Accounting Standards Codification (“ASC”) Topic 820, “Fair Value Measurement,” for the Company’s financial assets and liabilities that are re-measured and reported at fair value each reporting period and are re-measured and reported at fair value at least annually using a fair value hierarchy that is broken down into three levels. Level inputs are defined as follows:

Level 1 – quoted prices in active markets for identical assets or liabilities.

Level 2 – other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.

Level 3 – significant unobservable inputs that reflect management’s best estimate of what market participants would use to price the assets or liabilities at the measurement date.

At September 30, 2022 and December 31, 2021, the Company categorized its restricted cash of \$50,000 as Level 2 hierarchy. The assets classified as Level 2 have initially been valued at the applicable transaction price and subsequently valued, at the end of each reporting period, using other market observable data. Observable market data points include quoted prices, interest rates, reportable trades and other industry and economic events.

4. Leases

In January 2019, the Company amended the lease for its corporate headquarters and primary research facility in Marlborough, Massachusetts. The lease is for a total of 7,581 square feet of office and laboratory space and will expire on March 31, 2024. The lease contains an option to terminate after two 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 was not included in the lease liability on the Company’s balance sheet. The Company did not exercise its option to terminate in either the second or third year of the lease, and the option to terminate has expired. Additionally, the lease agreement did not contain information to determine the borrowing rate implicit in the lease. As such, the Company calculated its incremental borrowing rate based on what the Company would have to pay to borrow on a collateralized basis over the lease term for an amount equal to the remaining lease payments, taking into consideration such assumptions as, but not limited to, the U.S. treasury yield rate and borrowing rates from a creditworthy financial institution using the above lease factors.

The lease for our corporate headquarters represents 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 the lease term (number of years) and discount rate:

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Right of use asset	\$ 192	\$ 283
Liabilities		
Lease liability, current	132	125
Lease liability, non-current	70	170
Total lease liability	\$ 202	\$ 295
Lease Term and Discount Rate		
Weighted average remaining lease term	1.50	2.25
Weighted average discount rate	4.70%	4.70%

Operating lease costs included in operating expense were \$33,000 for the three months ended September 30, 2022 and 2021, respectively. Operating lease costs included in operating expense were \$99,000 for the nine months ended September 30, 2022 and 2021, respectively.

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 statements of cash flows was \$34,000 and \$44,000 for the three months ended September 30, 2022 and 2021, respectively. Cash paid for the nine months ended September 30, 2022 and 2021 was \$101,000 and \$110,000, 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, 2022 is as follows, in thousands:

2022 (remaining)	\$	34
2023		140
2024		35
Total lease payments		209
Less: Imputed interest		(7)
Total operating lease liabilities (includes current portion)	\$	<u>202</u>

5. Debt

In May 2020, the Company received loan proceeds pursuant to the Paycheck Protection Program (the "**PPP**") under the Coronavirus Aid, Relief, and Economic Security Act (the "**CARES Act**"). 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 the PPP loan proceeds received and accrued interest over the term of the loan. The Company believed it used the loan proceeds for eligible purposes and applied for full loan forgiveness. In February 2021, the Small Business Administration approved the Company's application for full loan forgiveness, and the full amount of the PPP loan was remitted to the lender for forgiveness. Upon loan forgiveness, the Company recognized a gain on the extinguishment of debt of \$233,000 for the loan proceeds received and interest accrued in the condensed consolidated statements of operations for the nine months ended September 30, 2021.

6. Stockholders' Equity

January 2021 Private Placement — On January 25, 2021, the Company completed a private placement of 4,420,863 shares of the Company's common stock at a purchase price per share of \$3.07, pre-funded warrants to purchase an aggregate of 140,065 shares of the Company's common stock (the "**January 2021 Pre-Funded Warrants**") at a purchase price per pre-funded warrant of \$3.069 and warrants to purchase an aggregate of 3,420,696 shares of the Company's common stock with an exercise price of \$3.00 per warrant (the "**January 2021 Warrants**") (the "**Private Placement**"). In connection with the Private Placement, the Company issued warrants to the placement agent, H.C. Wainwright & Co., LLC ("**HCW**"), to purchase a total of 342,070 shares of the Company's common stock at an exercise price of \$3.8375 per warrant (the "**January 2021 Placement Agent Warrants**"). Net proceeds to the Company from the Private Placement were \$12,669,000 after deducting placement agent fees and offering expenses.

February 2021 Registered Direct Offering — On February 17, 2021, the Company completed a registered direct offering of 2,246,784 shares of the Company's common stock at a purchase price of \$3.42 per share (the "**Offering**"). In connection with the Offering, the Company issued warrants to the placement agent, HCW, to purchase a total of 168,509 shares of the Company's common stock at an exercise price of \$4.275 per warrant (the "**February 2021 Placement Agent Warrants**"). Net proceeds to the Company from the Offering were \$6,908,000 after deducting placement agent fees and offering expenses.

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 were no instances outside of the Company’s control that could require cash settlement from any of the warrant series issued in the Company’s financing transactions, the Company’s outstanding warrants are outside the scope of ASC 480.

The Company then applies and follows the applicable accounting guidance in the FASB ASC Topic 815, “*Derivatives and Hedging*.” Financial instruments are accounted for as either derivative liabilities or equity instruments depending on the specific terms of the agreement. The warrants issued by the Company 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 are classified within stockholders’ equity.

The following table summarizes the Company’s outstanding equity-classified warrants at September 30, 2022:

Description	Exercise Price	Expiration Date	Balance	Warrants Issued	Warrants Exercised	Warrants Expired	Balance
			December 31, 2021				September 30, 2022
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 Warrants	\$ 4.00	2/13/2025	1,326,500	–	–	–	1,326,500
February 2020 Underwriter Warrants	\$ 5.00	2/11/2025	150,000	–	–	–	150,000
April 2020 Warrants	\$ 2.21	10/2/2025	428,266	–	–	–	428,266
April 2020 Placement Agent Warrants	\$ 2.9188	3/31/2025	41,756	–	–	–	41,756
January 2021 Warrants	\$ 3.00	7/27/2026	3,420,696	–	–	–	3,420,696
January 2021 Placement Agent Warrants	\$ 3.8375	7/27/2026	342,070	–	–	–	342,070
February 2021 Placement Agent Warrants	\$ 4.275	2/12/2026	168,509	–	–	–	168,509
			<u>6,544,070</u>	<u>–</u>	<u>–</u>	<u>–</u>	<u>6,544,070</u>

No warrants were exercised during the three months ended September 30, 2022 and 2021 and during the nine months ended September 30, 2022. The Company received net proceeds of \$2,146,000 from the exercise of warrants during the nine months ended September 30, 2021.

7. Net Loss per Common Share

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

	September 30,	
	2022	2021
Options to purchase common stock	1,708	2,499
Unvested restricted stock units	684,201	367,533
Warrants to purchase common stock	6,544,070	6,567,303
Total	<u>7,229,979</u>	<u>6,937,335</u>

8. Stock-based Compensation

Restricted Stock Units

Restricted stock units (“RSUs”) are issued under the Company’s 2020 Long-Term Incentive Plan (the “2020 Plan”) or as inducement grants issued outside of the 2020 Plan to new employees. RSUs are generally subject to graded vesting and the satisfaction of certain service requirements. Upon vesting, each outstanding RSU will be settled 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, 2022:

	Number of Shares	Weighted- Average Grant Date Fair Value Per Share
Unvested units at December 31, 2021	367,101	\$ 3.21
Granted	695,000	0.86
Vested	(168,090)	3.30
Forfeited	(209,810)	1.57
Unvested units at September 30, 2022	<u>684,201</u>	<u>\$ 1.30</u>

Stock-based compensation expense related to RSUs was \$98,000 and \$132,000 for the three months ended September 30, 2022 and 2021, respectively. Stock-based compensation expense related to RSUs was \$359,000 and \$313,000 for the nine months ended September 30, 2022 and 2021, respectively.

The aggregate fair value of awards that vested during the nine months ended September 30, 2022 and 2021 was \$138,000 and \$9,000, respectively, which represents the market value of the Company’s common stock on the date that the RSUs vested.

As of September 30, 2022, the compensation expense for all unvested RSUs in the amount of approximately \$677,000 will be recognized in the Company’s results of operations over a weighted average period of 1.86 years.

Stock Options

Stock options are issued under the 2020 Plan or as inducement grants issued outside of the 2020 Plan to new employees. Stock options are generally subject to graded vesting and the satisfaction of certain service requirements. Upon the exercise of a stock option, the Company issues new shares and delivers them to the recipient. The Company does not expect to repurchase shares to satisfy stock option exercises.

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 was 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. As the Company has limited stock option exercise information, the expected life assumption used 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 Company did not grant stock options during the three and nine months ended September 30, 2022 and 2021.

The following table summarizes the activity of the Company's stock options for the nine months ended September 30, 2022:

	Number of Shares	Weighted- Average Exercise Price Per Share	Aggregate Intrinsic Value
Balance at December 31, 2021	2,499	\$ 3,401.90	\$ —
Granted	—	—	—
Exercised	—	—	—
Cancelled	(791)	6,856.25	—
Balance at September 30, 2022	<u>1,708</u>	<u>\$ 1,802.14</u>	<u>\$ —</u>
Exercisable at September 30, 2022	<u>1,708</u>	<u>\$ 1,802.14</u>	<u>\$ —</u>

Stock-based compensation expense related to stock options for the three months ended September 30, 2022 and 2021 was \$5,000 and \$11,000, respectively. Stock-based compensation expense related to stock options for the nine months ended September 30, 2022 and 2021 was \$13,000 and \$29,000, respectively.

As of September 30, 2022, the compensation expense for all unvested stock options was recognized in the Company's results of operations.

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, 2022 and 2021, in thousands:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 54	\$ 36	\$ 163	\$ 80
General and administrative	49	107	209	262
Total stock-based compensation	<u>\$ 103</u>	<u>\$ 143</u>	<u>\$ 372</u>	<u>\$ 342</u>

9. Collaboration Agreements

In March 2021, the Company entered into a clinical co-development collaboration agreement with AgonOx, Inc. ("**AgonOx**"), a private company developing a pipeline of novel immunotherapy drugs targeting key regulators of the immune response to cancer. Under the clinical development agreement, the companies are working to develop a T cell-based therapy using the Company's lead product candidate, PH-762, and AgonOx's "double positive" TIL ("**DP TIL**") technology. Per the terms of the clinical development agreement, the Company committed to make future payments of up to \$4,000,000 to reimburse AgonOx for expenses incurred to support a clinical trial with AgonOx's DP TIL technology and PH-762. The Company will recognize its share of costs arising from research and development activities performed by AgonOx in the Company's financial statements in the period AgonOx incurs such expense. Phio will be entitled to certain future development milestones and low single-digit sales-based royalty payments from AgonOx's licensing of its DP TIL technology.

During the three and nine months ended September 30, 2022 and 2021, the Company did not incur research and development expense under the clinical development agreement.

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

In this report, “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, 2022 and results of operations for the three and nine months ended September 30, 2022 and 2021 should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission (the “SEC”) on March 22, 2022.

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,” “target,” “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 ongoing coronavirus pandemic, military conflict between Ukraine and Russia, inflationary pressures, rising interest rates, recession fears, the development of our product candidates, our ability to execute on business strategies, our ability to develop our product candidates with collaboration partners, and the success of any such collaborations, the timeline and duration for advancing our product candidates into clinical development, results from our preclinical and clinical activities, the timing or likelihood of regulatory filings and approvals, the success of our efforts to commercialize our product candidates if approved, our ability to manufacture and supply our product candidates for clinical activities, and for commercial use if approved, the scope of protection we are able to establish and maintain for intellectual property rights covering our technology platform, 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, 2021 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 except as required by law.

Overview

Phio Pharmaceuticals Corp. (“Phio,” “we,” “our” or the “Company”) strives to address the biggest challenges in immuno-oncology by working to create new pathways to a cancer-free future for patients. We are developing therapeutics that leverage our INTASYL™ technology to target both tumor and immune cells by regulating genes to strengthen a patient’s immune system while weakening tumor defense mechanisms. With our INTASYL self-delivering RNAi technology, we aim to bring the benefits of RNA therapeutics to the treatment of cancer where other modalities may be ineffective.

We are developing a pipeline of immuno-oncology therapies using our INTASYL technology, which are designed to attack cancers in multiple ways. Our INTASYL-based therapeutics are designed to: (1) directly modify cells in the tumor microenvironment (the “TME”) to weaken a tumor’s defense mechanisms and (2) strengthen immune cells, including those administered as part of adoptive cell therapy (“ACT”). We believe these two strategies will allow for multiple therapeutic applications of our INTASYL products.

In contrast to other RNA technologies and platforms, we believe the self-delivering nature of our INTASYL platform makes it ideally suited for direct therapeutic use, as well as for use with ACT treatments. Multiple inhibitory mechanisms restrain immune cells from effectively eradicating tumors, including immune checkpoints and reduced cell fitness and cell persistence. The immunosuppressive TME can pose a formidable barrier to immune cell infiltration and function. By using INTASYL-based therapeutics administered directly, we believe we can reprogram cells in the TME to help overcome these immunosuppressive mechanisms. Furthermore, by using our INTASYL technology during the manufacturing of ACT cell products we believe we can improve the characteristics and function of these cells, potentially leading to better therapeutic outcomes.

Direct Therapeutic Use of INTASYL

Cancer cells have evolved natural defenses that can suppress the immune system surrounding the tumor, an area called the TME, which decreases the effectiveness of many traditional immunotherapies. Reprogramming different cell types in the TME, such as cancer cells and immune cells, may overcome these natural tumor defenses and decrease resistance to immunotherapy. An optimal treatment therapy should have the ability to address targets both inside and on the surface of tumor and immune cells, creating multiple ways to prevent tumors from evading immune detection. Our INTASYL compounds can target both intracellular and extracellular genes and are being developed for use as direct therapeutics to reprogram the TME, including by local administration and activation of immune cells in the TME, and/or lowering the tumor cell's defenses. Therefore, we believe INTASYL-based therapeutics can be a novel way of fighting cancer by reprogramming the cells in the TME to make cancer more responsive to a patient's immune system and to other anti-cancer drugs.

Our lead product candidate, and our most advanced program in human clinical trials being developed by us in our direct therapeutic programs, is PH-762. PH-762 is an INTASYL compound designed to activate immune cells to better recognize and kill cancer cells by reducing the expression of the checkpoint protein PD-1, a clinically validated target for immunotherapy. Checkpoint proteins, such as PD-1, normally act as a type of "off switch" that prevent T cells, which are immune cells that protect the body from cancer cells and infections, from attacking certain cells in the body, such as cancer cells. The expression of PD-1 enables the cancer cell to evade the T cell. Reducing the expression of PD-1 can thereby reduce the ability of cancer cells to avoid T cell detection.

We have shown that we can reprogram the TME with PH-762 and achieve local activation of immune cells. Preclinical studies conducted by us demonstrated that local administration of PH-762 through intratumoral injection resulted in potent anti-tumoral effects. Treated animals showed a complete and statistically significant inhibition of tumor growth, whereas placebo treated animals displayed exponential tumor growth. *In vivo* data has shown that intratumoral treatment with PH-762 inhibits tumor growth in a dose dependent fashion in PD-1 responsive and refractory models. Furthermore, on-target activity was supported by modulation of immune cell populations toward anti-tumor phenotypes. Importantly, local administration of PH-762 resulted in activity against distant untreated tumors, indicative of a systemic anti-tumor response. We believe these data further support the potential for PH-762 to provide a strong local immune checkpoint blockade without the dose immune-related adverse effects seen with systemic antibody therapy.

In January 2022, we were granted clinical trial authorization by the French National Agency for the Safety of Medicines and Health Products to proceed with our first in-human clinical trial for PH-762 to treat subjects with melanoma at the Gustave Roussy Institute, one of the largest cancer centers in Europe. This first clinical trial with PH-762 is a Phase 1b study to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of PH-762 in a neoadjuvant setting in subjects with advanced melanoma. Currently, there are no neoadjuvant treatment options approved for these subjects. The clinical trial features a dose escalation of PH-762 monotherapy with a maximum of 5 dose escalation cohorts and up to a maximum of 21 subjects. Subjects eligible for enrollment include those with Stage IIIB/IIIC or Stage IV resectable oligometastatic melanoma. Enrolled subjects receive a weekly dose of PH-762 for four weeks and receive surgical resection surgery of their tumor(s) four weeks after treatment with PH-762. The clinical trial design allows for a data driven evaluation of the recommended Phase 2 dose. We have initiated dosing of subjects and the site is open for continued enrollment. We anticipate top-line data from the first group of subjects in the first quarter of 2023, however, the impact of the ongoing coronavirus pandemic on the enrollment of subjects in the clinical trial is not yet known and highly difficult to predict; and therefore, may result in delays to our expected timelines.

Our second direct therapeutic product candidate is PH-894. PH-894 is an INTASYL compound designed to silence the epigenetic protein BRD4, which is an intracellular regulator of gene expression that impacts cell differentiation, and hence, cell function. Like other epigenetic targets, BRD4 is a protein that has been shown to be difficult to target with current drug modalities. Since BRD4 is an intracellular protein, antibody therapies cannot be used and small molecule inhibitors tested to date typically lack the required specificity.

We have presented data demonstrating that PH-894 resulted in a strong, concentration dependent and durable silencing of BRD4 in T cells, and in various cancer cells. Data published with PH-894 in a hepatocellular carcinoma model demonstrated potent and statistically significant anti-tumoral effects when administered locally. These data show that our PH-894 compound can reprogram T cells and other cells in the TME to provide enhanced therapeutic activity. Similar to PH-762, we have shown that local administration of PH-894 *in vivo* has resulted in a systemic anti-tumor response. After local administration of PH-894 in *in vivo* studies conducted in colon and liver cancer models, strong anti-tumor activity was seen in directly treated and in distant untreated tumors. Additionally, PH-894 enhanced the anti-tumor activity of systemic anti-PD-1 antibody therapy for both the locally treated tumors and the untreated tumors. With these data, there is potential for PH-894 to be used in treating patients who do not respond to anti-PD-1 therapy, or with patients who progress after initially responding to such therapy. PH-894 demonstrates the power of our INTASYL compounds to modulate the expression of intracellular and/or commonly considered “undruggable” targets, a limitation for small molecule and antibody therapies. We currently expect to finalize IND-enabling studies for PH-894 in the fourth quarter of 2022.

Use of INTASYL To Improve Adoptive Cell Therapy Products

ACT consists of the administration of immune cells with antitumor properties to patients to fight cancer after growing the cells in a lab to large numbers. There are several types of ACT, including: (1.) 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 or macrophages and (2.) 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, chimeric antigen receptor (“**CAR**”) T cells, or CAR-NK cells).

Regardless of the source, most of the immune cells used for ACT have several shortcomings that inhibit their full therapeutic potential in patients with solid tumors, which we believe can be overcome with INTASYL-based therapeutics. For example, multiple inhibitory mechanisms restrain immune cells used in ACT from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence in addition to other barriers to immune cell infiltration and function occurring mainly in solid tumors. When used in ACT, we believe our INTASYL compounds can improve immune cell function, differentiation and metabolism, 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*, or outside the body, while they are growing in the lab and before administering them to the patient. In contrast to other RNA technologies, our INTASYL compounds do not require a delivery vehicle or specialized delivery tools to deliver the RNA drugs into the cells. Therefore, 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, complex delivery vehicles or formulations, or additional complex manufacturing steps, which in themselves may be detrimental to the cells. 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.

Our lead product candidate, and our most advanced program being developed by us in ACT, is PH-762. Data has demonstrated that PH-762 silences PD-1 checkpoint expression in T cells, thereby removing the “off switch” and enabling T cells to overcome tumor resistance mechanisms, which improves their ability to destroy tumor cells. Preclinical studies have shown that PH-762 can silence the expression of PD-1 in target human T cells in a potent and durable manner and can increase their tumor cell-killing ability. Patient derived T cells treated with PH-762, in comparison to untreated T cells, were shown to have increased tumor killing potency against tumor cells of the same patient. As a result, we believe that PH-762 in ACT is well-positioned to enhance therapeutic responses in cancer patients.

In March 2021, we entered into a clinical co-development collaboration agreement (the “**Clinical Agreement**”) with AgonOx, Inc. (“**AgonOx**”) to develop novel T cell-based therapies using PH-762 and AgonOx’s “double positive” TIL (“**DP TIL**”) technology. AgonOx has demonstrated that its DP TIL enriched cell populations have increased tumor killing activity when compared to TILs that were not enriched prior to expansion. Further, preclinical data from our research collaboration with AgonOx has shown that treating DP TILs with PH-762 increases the tumor killing activity of the DP TILs even further (a two-fold increase). As a result, we expect the use of PH-762 treated DP TILs to enhance therapeutic responses in cancer patients. Based on these data, our collaboration with AgonOx will focus on conducting a clinical trial for PH-762 treated DP TILs. Under the Clinical Agreement, we will provide financial support of up to \$4 million to AgonOx to conduct a clinical trial in ACT with their DP TIL technology and PH-762. We will be entitled to certain future development milestones and low single-digit sales-based royalty payments from AgonOx’s licensing of its DP TIL technology. Financial support to AgonOx under the Clinical Agreement has not yet commenced. We expect to initiate the clinical trial evaluating the use of PH-762 and DP TILs in ACT in the fourth quarter of 2022.

Our second product candidate in development for use in ACT is PH-894. As our INTASYL compounds can address intracellular as well as extracellular gene targets with a high level of specificity, we believe there is potential for PH-894 to play a role in boosting the potency of the next generation of T cell products to enhance ACT for solid tumors, and without using genetic manipulation. 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). Recent preclinical data was presented showing that silencing BRD4 with PH-894 may be used to improve the characteristics of CAR-T cell products during the activation and expansion phases of the cell manufacturing process. These data demonstrate that PH-894 could enhance the activity of CAR-T cells by improving the quality of the final CAR-T cell product by overcoming immunosuppression, reversing exhaustion, and preserving the characteristics associated with cell persistence.

Impact of the Coronavirus Pandemic

We continue to respond to and monitor the ongoing coronavirus pandemic. Our corporate headquarters and research facility have seen limited impact and, during the three and nine months ended September 30, 2022, continued to operate with safety measures in place for the health and well-being of our employees, such as working remotely and flexible scheduling, in accordance with guidance from federal, state and local authorities. We believe that that coronavirus pandemic has not had a significant impact on our financial condition and results of operations for the three and nine months ended September 30, 2022.

However, the extent to which the coronavirus pandemic may materially impact our financial results and operations will depend on a number of factors, including the availability of supplies and services we rely on, the ability to enroll subjects in our clinical trials, the emergence of variant strains of the coronavirus, the development, availability, and public acceptance of effective treatments and vaccines, and the duration of the coronavirus pandemic, which remain difficult to predict and are highly uncertain. 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 potential economic impact brought by the coronavirus pandemic, which may be exacerbated by the global macroeconomic uncertainty from the ongoing conflict between Russia and Ukraine, is difficult to assess or predict. There may be developments outside of our control that require us to adjust our operating plans. Given the nature of the situation, we cannot reasonably estimate the impact of the coronavirus pandemic on our financial condition, results of operations or cash flows in the future.

Impact of Inflation

Inflation has increased during the period covered by this report and is expected to continue to remain at elevated levels or even increase for the near future. Inflation generally affects us by increasing our cost of labor and third party contract costs. We do not believe inflation has had a material effect on our results of operations during the three and nine months ended September 30, 2022.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated 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 material changes to our critical accounting policies and estimates as compared to those disclosed in the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2021.

Results of Operations

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

Description	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Dollar Change	2022	2021	Dollar Change
Operating expenses	\$ 3,571	\$ 3,739	\$ (168)	\$ 8,732	\$ 10,061	\$ (1,329)
Operating loss	(3,571)	(3,739)	168	(8,732)	(10,061)	1,329
Net loss	\$ (3,576)	\$ (3,742)	\$ 166	\$ (8,749)	\$ (9,836)	\$ 1,087

Comparison of the Three and Nine Months Ended September 30, 2022 and 2021

Operating Expenses

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

Description	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Dollar Change	2022	2021	Dollar Change
Research and development	\$ 2,508	\$ 2,673	\$ (165)	\$ 5,398	\$ 6,661	\$ (1,263)
General and administrative	1,063	1,066	(3)	3,334	3,400	(66)
Total operating expenses	\$ 3,571	\$ 3,739	\$ (168)	\$ 8,732	\$ 10,061	\$ (1,329)

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, research activities under our research collaborations, expenses associated with preclinical and clinical development activities and other operating costs. Our research and development programs are focused on the development of immunoncology therapeutics based on our INTASYL therapeutic platform. Since we commenced operations, research and development expenses have been a significant portion of our total operating expenses and are expected to constitute the majority of our spending for the foreseeable future.

Research and development expenses for the three months ended September 30, 2022 decreased 6% as compared with the three months ended September 30, 2021. The decrease in research and development expenses was primarily due to manufacturing costs for PH-762 and PH-894 totaling approximately \$828,000 and the expense of \$736,000 related to the preclinical studies required for our PH-762 intratumoral clinical trial incurred in the prior year period offset by increases in research and development expenses for the preclinical studies required for our planned clinical trial with PH-894 conducted in the current year period of approximately \$1,465,000.

Research and development expenses for the nine months ended September 30, 2022 decreased 19% as compared with the nine months ended September 30, 2021. The decrease in research and development expenses was primarily due to manufacturing costs for PH-762 and PH-894 totaling approximately \$1,296,000 and the expense of \$1,717,000 related to the preclinical studies required for our PH-762 intratumoral clinical trial incurred in the prior year period offset by increases in research and development expenses for the preclinical studies required for our planned clinical trial with PH-894 conducted in the current year period of approximately \$1,500,000 and PH-762 intratumoral clinical trial expenses of \$253,000.

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 September 30, 2022 overall were consistent with the three months ended September 30, 2021. The decrease in our payroll-related expenses as a result of the departure of our former Chief Executive Officer of \$103,000 were offset by increases in legal fees of \$44,000 and the use of outside consultants to support operations of \$55,000.

General and administrative expenses for the nine months ended September 30, 2022 decreased 2% as compared with the nine months ended September 30, 2021. The decrease in general and administrative expenses was primarily due to decreases in legal and patent fees of approximately \$197,000 offset by increases in Board of Directors and recruiting fees of \$114,000 to support our operations as a result of the departure of our former Chief Executive Officer.

Total Other (Expense) Income

Total other expense for the three months ended September 30, 2022 and 2021 was consistent quarter over quarter. Total other income for the nine months ended September 30, 2022 decreased by \$242,000 as compared with the nine months ended September 30, 2021, primarily due to the full forgiveness of the Company's Paycheck Protection Program ("**PPP**") loan in the first quarter of 2021.

Liquidity and Capital Resources

Historically, our primary source of funding has been through the sale of our 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. 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. At September 30, 2022, we had cash of \$14,484,000 as compared with \$24,057,000 at December 31, 2021.

We believe that our existing cash at September 30, 2022 should be sufficient to fund operations for at least the next 12 months from the date of the release of the associated financial statements.

For information regarding our cash commitments related to the clinical co-development agreement with AgonOx, see Note 9 to our condensed consolidated financial statements.

In August 2019, we entered into a purchase agreement (the “**Purchase Agreement**”) with Lincoln Park Capital, LLC (“**LPC**”), pursuant to which we had the right to sell to LPC up to \$10,000,000 in shares of our common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. The Purchase Agreement expired in May 2022 and no shares of common stock were sold to LPC under the Purchase Agreement.

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

	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	\$ (9,424)	\$ (9,387)
Net cash used in investing activities	(121)	(51)
Net cash (used in) provided by financing activities	(28)	21,723
Net (decrease) increase in cash and restricted cash	<u>\$ (9,573)</u>	<u>\$ 12,285</u>

Net Cash Flow from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022 increased as compared with the nine months ended September 30, 2021, primarily due to an increase of \$1,392,000 in the changes in operating assets and liabilities primarily due to payments made for the required preclinical studies for PH-894 and for the manufacturing of clinical supply batches of PH-762 and PH-894 offset by decreases in net loss of \$1,087,000 and non-cash related items of \$268,000 as a result of the full forgiveness of the Company’s PPP loan in the prior year period offset.

Net Cash Flow from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 increased as compared with the nine months ended September 30, 2021, primarily due to an increase of \$70,000 in purchases of laboratory and computer equipment for the Company’s facility as compared to the prior year period.

Net Cash Flow from Financing Activities

Net cash from financing activities for the nine months ended September 30, 2022 decreased as compared with the nine months ended September 30, 2021, primarily due to the net proceeds of \$21,723,000 received by the Company from capital raising activities and warrant exercises in the comparable prior year period.

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 interim Principal Executive Officer (who is also acting as our principal financial officer) and our Principal Accounting Officer, evaluated the effectiveness of 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 interim Principal 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 at the reasonable assurance level 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 quarter ending September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become a party to various legal proceedings and complaints arising in the ordinary course of business. To our knowledge, we are not currently a party to any actual or threatened material legal proceedings.

ITEM 1A. RISK FACTORS

Our business, financial condition or results of operations could be materially adversely affected by the risks set forth in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 22, 2022, our Quarterly Report on Form 10-Q for the period ended March 31, 2022 filed with the SEC on May 12, 2022 and our Quarterly Report on Form 10-Q for the period ended June 30, 2022 filed with the SEC on August 11, 2022. There have been no material changes from those risk factors, except for the additional risk factor set forth below. 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. Additional risks not currently known or currently material to us may also harm our business.

We may not be able to regain compliance with the continued listing requirements of The Nasdaq Capital Market.

On February 25, 2022, we received written notice (the “**First Notification Letter**”) from the Listings Qualifications Department of The Nasdaq Stock Market LLC (“**Nasdaq**”) notifying us that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) (the “**Minimum Bid Price Rule**”) for continued listing on The Nasdaq Capital Market. The Minimum Bid Price Rule requires listed securities to maintain a minimum bid price of \$1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of our common stock for the 30 consecutive business days prior to the date of the First Notification Letter, we no longer met the minimum bid price requirement. The First Notification Letter stated that the Company had 180 days, or until August 24, 2022, to demonstrate its compliance with the Minimum Bid Price Rule.

On August 25, 2022, we received a second written notice (the “**Second Notification Letter**” and, together with the First Notification Letter, the “**Notification Letters**”) from Nasdaq advising that we had been granted an additional 180 calendar days, or to February 20, 2023, to regain compliance with the Minimum Bid Price Rule, in accordance with Nasdaq Listing Rule 5810(c)(3)(A). According to the Second Notification Letter, if at any time before that date the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will notify us that we have achieved compliance with the Minimum Bid Price Rule.

The Notification Letters do not impact our listing on The Nasdaq Capital Market or trading of our common stock at this time. In the event that we do not regain compliance by February 20, 2022, Nasdaq will provide notice that our common stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will be able to regain compliance with the Minimum Bid Price Rule. However, if we fail to regain compliance with the Minimum Bid Price Rule or fail to maintain compliance with all other applicable continued listing requirements and Nasdaq determines to delist our common stock, the delisting could adversely impact us by, among other things, reducing the liquidity and market price of our common stock; reducing the number of investors willing to hold or acquire our common stock; limiting our ability to issue additional securities in the future; and limiting our ability to fund our operations.

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

No sales or issuances of unregistered securities occurred that have not previously been disclosed in a Current Report on Form 8-K.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS**EXHIBIT INDEX**

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
31.1	<u>Sarbanes-Oxley Act Section 302 Certification of Principal Executive Officer and Principal Financial Officer.</u> *		
32.1	<u>Sarbanes-Oxley Act Section 906 Certification of Principal Executive Officer and Principal Financial Officer.</u> **		
101.INS	Inline XBRL Instance Document.*		
101.SCH	Inline XBRL Taxonomy Extension Schema Document.*		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*		
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*		
104	The cover page for this report, formatted in Inline XBRL (included in Exhibit 101).*		

* Filed herewith.

** Furnished herewith and not deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section or incorporated by reference into any filing under the Securities Act or the Exchange Act.

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/ Robert Bitterman

Robert Bitterman

Interim Executive Chairman (interim principal executive officer and interim principal financial officer)

Date: November 10, 2022

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a)
AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert Bitterman, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 10, 2022

/s/ Robert Bitterman

Robert Bitterman
Interim Executive Chairman

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

In connection with the Quarterly Report on Form 10-Q of Phio Pharmaceuticals Corp. (the “Company”) for the period ended September 30, 2022 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.

Dated: November 10, 2022

/s/ Robert Bitterman

Robert Bitterman

Interim Executive Chairman