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

FORM 8-K

CURRENT REPORT

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

Date of report (Date of earliest event reported): November 10, 2022

PHIO PHARMACEUTICALS CORP.

(Exact name of registrant as specified in its charter)

Delaware	**001-36304**	**45-3215903**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

257 Simarano Drive, Suite 101
Marlborough, Massachusetts 01752
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (508) 767-3861

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class of securities:	Trading Symbol(s):	Name of exchange on which registered:
Common Stock, par value $0.0001	PHIO	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.02. Results of Operations and Financial Condition.

On November 10, 2022, Phio Pharmaceuticals Corp. reported its financial results for the period ended September 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Report").

The information in this Item 2.02 and attached as Exhibit 99.1 to this Report will not be treated as "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. This information will not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or into another filing under the Exchange Act, unless that filing expressly incorporates this information by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 10, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

PHIO PHARMACEUTICALS CORP.

Date: November 10, 2022

By: /s/ Robert Bitterman
Name: Robert Bitterman
Title: Interim Executive Chairman

Exhibit 99.1

Phio Announces New Appointments to Leadership Team, Reports on Third Quarter 2022 Financial Results and Provides Business Update

New executive team leading development of Phio's RNAi compounds and proprietary INTASYL™ platform

Continuing enrollment in its Phase 1b study of PH-762 for the treatment of advanced melanoma

Additional studies demonstrate INTASYL's activity against multiple protein targets including PD-1, BRD4, CTLA4, TIGIT and CTGF

MARLBOROUGH, Mass., November 10, 2022 /PRNewswire—Phio Pharmaceuticals Corp. (Nasdaq: PHIO), today announced new appointments to the leadership team, reported its financial results for the quarter ended September 30, 2022 and provided a business update. Phio is a clinical stage biotechnology company whose proprietary INTASYL™ technology makes immune cells more effective in killing tumor cells. INTASYL is the only self-delivering RNAi technology focused on immuno-oncology therapeutics.

The continuing enrollment in its first-in-human clinical study of PH-762 for advanced melanoma, along with recent positive data from four of its preclinical studies, has attracted new and industry-experienced executives to the Company. The new leadership team will join the current executive team to move the Company forward as it evolves its proprietary platform, INTASYL, from discovery to development.

The newly expanded leadership team is led by industry veteran Robert Bitterman, a member of the board of directors since 2012. Appointed Executive Chairman in September of this year, he assumed the duties leading all aspects of the Company's operations. Mr. Bitterman brings 25 years of executive leadership experience in the pharmaceutical and biologic life science industry. He also has prior experience in senior financial and investor relations roles.

A key part of this new leadership team includes the appointment of Linda Mahoney as Vice President of Project Development, where she will lead the coordination of a multifunctional team to advance INTASYL compounds through the clinical development process. Ms. Mahoney is a pharmaceutical development executive with more than 25 years of experience in the industry. Previously, Ms. Mahoney was Vice President of Scientific Operations and Business Development at Cutanea Life Sciences, Inc. She also held positions in project management, product development and commercial supply chain at Sanofi-Aventis. Ms. Mahoney led numerous cross-functional pharmaceutical project teams through all stages of development, from product concept through commercialization.

Supporting the leadership team through the clinical development process is Dr. Mary Spellman, a board-certified dermatologist. Dr. Spellman will be working with the Company as a medical advisor and clinical development consultant. Dr. Spellman recently served as Chief Medical Officer at Castle Creek Biosciences, and prior to that at Menlo Therapeutics. She has contributed to the initiation of numerous Investigational New Drug applications, and to multiple drug and biologic marketing applications in a spectrum of clinical indications. Dr. Spellman is a Fellow of the American Academy of Dermatology, and currently is President of the Dermatologists in Industry organization. She is a former Associate Editor and now is a Reviewer for the Journal of the American Academy of Dermatology.

Phio's business development activities will be supplemented by Michael Cozart, Managing Partner at LifeSci Consulting, LLC, a global strategy, consulting, and transaction advisory firm.

Recent Corporate Updates

- Phio's research partner, Helmholtz Munich, presented preclinical data on Phio's lead clinical product PH-762, an INTASYL compound targeting PD-1, at the 9th Immunotherapy of Cancer (ITOC) annual meeting. PH-762 demonstrated increases in T cell population expressing stem-cell like characteristics. This increase in T cell population is expected to improve T cell persistence *in vivo*, therefore, resulting in enhanced duration of anti-tumor activity.
- At the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), Phio presented four posters demonstrating anti-tumor activity in preclinical models with our INTASYL compounds silencing the proteins BRD4, CTLA4, TIGIT and CTGF. Also, in preparation for an upcoming clinical trial in collaboration with our partner AgonOx, Inc., a poster demonstrating ability to manufacture clinical scale grade TIL with and without PH-762, our INTASYL compound targeting PD-1 was presented. An additional poster reported on the clinical trial design and update on the enrollment in our Phase 1b study of PH-762 for the treatment of advanced melanoma.

Upcoming Pipeline Milestones

- Plans to initiate a clinical trial evaluating the use of PH-762 and DP TIL in ACT during the fourth quarter of 2022 in partnership with AgonOx, Inc.
- Expects to finalize IND-enabling studies for PH-894 by year end 2022
- Expects to report top-line data from the first group of subjects with advanced melanoma in the clinical trial for PH-762 in the first quarter of 2023
- Additional data publications on the Company's pipeline programs

Financial Results

Cash Position

At September 30, 2022, the Company had cash of $14.5 million as compared with $24.1 million at December 31, 2021. The Company expects its current cash will be sufficient to fund currently planned operations for at least the next 12 months.

Research and Development Expenses

Research and development expenses decreased 6% to approximately $2.5 million for the quarter ended September 30, 2022, compared with approximately $2.7 million for the quarter ended September 30, 2021. The decrease in research and development expenses was primarily due manufacturing costs for PH-762 and PH-894 and the preclinical studies required for the Company's PH-762 intratumoral clinical trial that were incurred in the prior year period offset by increases in research and development expenses for the preclinical studies required for the Company's planned clinical trial with PH-894 conducted in the current year period.

General and Administrative Expenses

General and administrative expenses were approximately $1.1 million for the quarters ended September 30, 2022 and 2021 and were consistent quarter over quarter.

Net Loss

Net loss decreased 4% to approximately $3.6 million, or $0.26 per share, for the quarter ended September 30, 2022, compared with $3.7 million, or $0.28 per share, for the quarter ended September 30, 2021. The decrease in net loss was primarily attributable to the decrease in research and development expenses as described above.

About INTASYL

INTASYL is the only self-delivering RNAi technology focused on immuno-oncology therapeutics. INTASYL compounds are chemically modified siRNA's that provide efficient, spontaneous cellular uptake and potent, long lasting intracellular activity targeting a broad range of cell types and tissues. INTASYL drugs precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems. In comparison to biologics and cell and gene therapies, INTASYL has a favorable non-clinical toxicity and safety profile, and a streamlined chemical synthesis that reduces costs and offers substantial convenience to the prescriber and patient.

PH-762 is an INTASYL compound that reduces the expression of PD-1, a protein that inhibits T cells' ability to kill cancer cells. By suppressing PD-1, the T cells are re-activated to kill cancer cells. PH-762 is being developed as a standalone drug therapy (Direct-to-Tumor) and also in combination with adoptive cell therapy. PH-762 is in a Phase 1b study for the treatment of advanced melanoma.

PH-894 is an INTASYL compound that silences BRD4, a protein that controls gene expression in both T cells and tumor cells, thereby effecting the immune system as well as the tumor. What sets this compound apart is its dual mechanism: INTASYL PH-894 suppression of BRD4 in T cells results in T cell activation; additionally, suppression of BRD4 in tumor cells results in tumors becoming more sensitive to T-cell killing.

PH-804 is an INTASYL compound that targets TIGIT, a protein that inhibits the activity of Natural Killer (NK) cells. A recent study demonstrated that NK cells, when treated with PH-804, increased activation and enhanced the ability of NK cells to kill cancer cells.

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a clinical stage biotechnology company whose proprietary INTASYL™ RNAi technology makes immune cells more effective in killing tumor cells. INTASYL is the only self-delivering RNAi technology focused on immuno-oncology therapeutics. INTASYL drugs precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems.

For additional information, visit the Company's website, www.phiopharma.com.

Forward Looking Statements

This press release 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. Our actual results may differ materially from those indicated in the forward-looking statements as a result of a number of important factors, including, but 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, results from our preclinical and clinical activities, 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, 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, our ability to obtain future financing, market and other conditions and those identified in our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q under the caption "Risk Factors" and in other filings the company periodically makes with the SEC. Readers are urged to review these risk factors and to not act in reliance on any forward-looking statements, as actual results may differ from those contemplated by our forward-looking statements. Phio does not undertake to update forward-looking statements to reflect a change in its views, events or circumstances that occur after the date of this release, except as required by law.

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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	3,571	3,739	8,732	10,061
Operating loss	(3,571)	(3,739)	(8,732)	(10,061)
Total other (expense) income, net	(5)	(3)	(17)	225
Net loss	$ (3,576)	$ (3,742)	$ (8,749)	$ (9,836)
Net loss per common share: Basic and diluted	$ (0.26)	$ (0.28)	$ (0.64)	$ (0.78)
Weighted average number of common shares outstanding: Basic and diluted	13,662,857	13,534,560	13,628,931	12,593,569

PHIO PHARMACEUTICALS CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands)
(Unaudited)

	September 30, 2022	December 31, 2021
ASSETS		
Cash	$ 14,484	$ 24,057
Restricted cash	50	50
Prepaid expenses	843	620
Right of use asset, net	192	283
Property and equipment, net	198	133
Other assets	24	27
Total assets	$ 15,791	$ 25,170
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 543	$ 283
Accrued expenses	1,519	2,660
Lease liability	202	295
Total stockholders' equity	13,527	21,932
Total liabilities and stockholders' equity	$ 15,791	$ 25,170