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): August 11, 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 August 11, 2022, Phio Pharmaceuticals Corp. reported its financial results for the period ended June 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 August 11, 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: August 11, 2022

By: /s/ Geert Cauwenbergh
Geert Cauwenbergh, Dr. Med. Sc.
Principal Executive and Financial Officer, Director

Exhibit 99.1

Phio Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Business Update

Initiated dosing of subjects and enrollment ongoing in the first-in-human clinical study of PH-762 for the treatment of advanced melanoma; expect to announce top-line data from the first group of subjects in Q1 2023

Expects to initiate a clinical trial evaluating the use of PH-762 and "double positive" tumor infiltrating lymphocytes ("DP TILs") in adoptive cell therapy ("ACT") in Q4 2022 in partnership with AgonOx

Expects to finalize IND-enabling studies for PH-894 in Q4 2022

Controlled R&D spending in the first half of the year with reduced net loss per share versus same period last year; expects current cash to fund planned operations to Q4 2023

Marlborough, Mass., August 11, 2022/PRNewswire/ -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a clinical stage biotechnology company developing the next generation of therapeutics based on its proprietary self-delivering RNAi (INTASYL™) therapeutic platform, today reported its financial results for the quarter ended June 30, 2022 and provided a business update.

"We are pleased to have initiated our first-in-human clinical trial of PH-762, while maintaining our spending in the first half of the year. This clinical trial evaluates the safety, tolerability, pharmacokinetics and checkpoint anti-tumor activity of PH-762 in a neoadjuvant setting in subjects with advanced melanoma. This study will feature a dose escalation of PH-762 with top-line data from the first group of patients expected in the first quarter of 2023," said Dr. Geert Cauwenbergh, Principal Executive Officer of Phio. "We look forward to achieving a number of milestones during the second half of 2022, including the planned initiation of our first clinical trial in ACT with PH-762 in partnership with AgonOx, Inc. This trial will evaluate the safety, tolerability and efficacy of DP TILs treated with PH-762 in subjects with advanced metastatic melanoma. We also continue to generate promising new data for our preclinical programs, both in collaboration with our partners and on our own. We expect to present these new data during several presentations at major conferences in the second half of this year."

Quarter in Review and Recent Corporate Updates

- Initiated dosing of subjects and enrollment ongoing in a Phase 1b clinical study to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of PH-762 in a neoadjuvant setting in subjects with advanced melanoma.
- Presented new preclinical data at the American Society of Gene & Cell Therapy (ASGCT) 25th Annual Meeting which show silencing BRD4 with PH-894, a self-delivering RNAi INTASYL compound, can be used to improve the characteristics of CAR-T cell products during the activation and expansion phases of the cell manufacturing process.
- Presented a trial-in-progress poster describing the study outline of a Phase 1b clinical trial of PH-762, a self-delivering RNAi targeting PD-1, for the treatment of advanced melanoma at the 2022 American Society of Clinical Oncology (ASCO) annual meeting. As there is currently no neoadjuvant standard of care for resectable advanced melanoma patients, neoadjuvant treatment with PH-762 provides an alternative therapeutic option to treat these patients.

Upcoming Pipeline Milestones

- Plans to initiate a clinical trial evaluating the use of PH-762 and DP TILs in ACT during the fourth quarter of 2022 in partnership with AgonOx, Inc.
- Expects to finalize IND-enabling studies for PH-894 in the second half of 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 June 30, 2022, the Company had cash of $18.0 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 to the fourth quarter of 2023.

Research and Development Expenses

Research and development expenses decreased 16% to approximately $1.3 million for the quarter ended June 30, 2022, compared with approximately $1.6 million for the quarter ended June 30, 2021. The decrease in research and development expenses was primarily due to the completion of the preclinical studies with PH-762 required for the Company’s clinical trial as a direct therapeutic and the manufacturing costs of PH-894 in the prior year period offset by an increase in personnel-related expenses as a result of a higher headcount.

General and Administrative Expenses

General and administrative expenses increased 8% to approximately $1.2 million for the quarter ended June 30, 2022, compared with approximately $1.1 million for the quarter ended June 30, 2021. The increase in general and administrative expenses was primarily due to a total net increase in payroll and executive search-related expenses as a result of the departure of the Company’s CEO.

Net Loss

Net loss decreased 6% to approximately $2.5 million, or $0.19 per share, for the quarter ended June 30, 2022, compared with $2.7 million, or $0.20 per share, for the quarter ended June 30, 2021. The decrease in net loss was primarily attributable to the decrease in research and development, which was partially offset by an increase in general and administrative expenses as described above.

For the six months ended June 30, 2022, the Company saw a decrease of 15% in net loss to approximately $5.2 million, or $0.38 per share, compared with approximately $6.1 million, or $0.50 per share, for the six months ended June 30, 2021. The decrease in net loss was primarily attributable to a decrease in research and development expenses driven by the completion of the preclinical studies with PH-762 required for the Company’s clinical trial as a direct therapeutic and the manufacturing costs for PH-762 and PH-894 offset by an increase in personnel-related expenses as a result of a higher headcount and increased third-party professional service fees as the Company prepared for and began its clinical trial with PH-762.

About PH-762

PH-762 activates immune cells to better recognize and kill cancer cells. It does so by reducing the expression of PD-1, a clinically validated target for immunotherapy. PD-1 is expressed by T cells and prevents them from killing cancer cells. When PH-762 reduces PD-1 expression, the "brakes" on the immune system are released and activates the T cells to kill the cancer cells. PH-762 is being developed as a standalone drug therapy with local intratumoral administration to a tumor. In addition, it is also being developed as a critical component of cellular immunotherapy, more specifically to improve tumor cell killing capability of adoptively transferred tumor infiltrating lymphocyte (TIL) therapy.

About PH-894

PH-894 silences 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. PH-894 is being developed as a standalone drug therapy with local intratumoral administration to a tumor. In addition, it is also being developed as a critical component of cellular immunotherapy.

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a clinical stage 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 microenvironment. Our goal is to develop powerful INTASYL therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby providing patients a powerful new treatment option that goes beyond current treatment modalities. 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 1,304	$ 1,559	$ 2,890	$ 3,988
General and administrative	1,217	1,125	2,271	2,334
Total operating expenses	2,521	2,684	5,161	6,322
Operating loss	(2,521)	(2,684)	(5,161)	(6,322)
Total other (expense) income, net	(10)	(3)	(12)	228
Net loss	$ (2,531)	$ (2,687)	$ (5,173)	$ (6,094)
Net loss per common share: Basic and diluted	$ (0.19)	$ (0.20)	$ (0.38)	$ (0.50)
Weighted average number of common shares outstanding:				
Basic and diluted	13,658,722	13,534,389	13,611,687	12,115,276

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

	June 30, 2022	December 31, 2021
ASSETS		
Cash	$ 18,020	$ 24,057
Restricted cash	50	50
Prepaid expenses	1,618	620
Right of use asset, net	223	283
Property and equipment, net	206	133
Other assets	27	27
Total assets	$ 20,144	$ 25,170
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 1,148	$ 283
Accrued expenses	1,759	2,660
Lease liability	234	295
Total stockholders' equity	17,003	21,932
Total liabilities and stockholders' equity	$ 20,144	$ 25,170