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, 2021

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

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, 2021, Phio Pharmaceuticals Corp. reported its financial results for the period ended September 30, 2021. A copy of the press released 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, 2021.
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, 2021

By: /s/ Gerrit Dispersyn
Gerrit Dispersyn
President and Chief Executive Officer

Exhibit 99.1

Phio Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Business Update

Lead program, PH-762, is on track to enter first-in-human clinical study in Q1 2022

Presented data at the ESMO Congress 2021 showing Dual-Targeting INTASYL PH-3861 induced a durable and specific systemic anti-tumor immune response following local administration

Marlborough, Mass., November 10, 2021/PRNewswire/ -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a biotechnology company developing the next generation of immuno-oncology therapeutics based on its proprietary self-delivering RNAi (INTASYL™) therapeutic platform, today reported its financial results for the quarter ended September 30, 2021 and provided a business update.

"Our development programs continue to generate positive *in vivo* data showing how INTASYL technology can be utilized in various applications to treat cancer. These data have generated broad interest in our programs as we prepare to enter the clinic with the initiation of two trials expected in the next couple of quarters," said Dr. Gerrit Dispersyn, President and CEO of Phio. "We expect to initiate our first-in-human clinical study of our lead program, PH-762, in the first quarter of 2022, which will be followed by the first study with PH-762-empowered tumor infiltrating lymphocyte therapy to start in Q2. In addition, we've generated a lot of exciting *in vivo* data in support of the development of our PH-894 compound, showing it provides enhanced immunotherapeutic activity by reprograming T cells and other cells in the TME, and supporting our plans to file for a clinical trial application with the FDA in the second half of 2022."

Quarter in Review and Recent Corporate Updates

- Presented positive data from several *in vivo* preclinical studies demonstrating the flexibility and application of INTASYL in the field of immuno-oncology at leading scientific conferences held during the third quarter of 2021:
  - Announced new data showing that local treatment *in vivo* with INTASYL has the potential to cure locally treated and distal untreated tumors and generate systemic tumor immunity that is both durable and tumor specific, further highlighting the technology's potential in direct therapeutic applications. Data from this study, presented at the European Society of Medical Oncology (ESMO) Congress 2021, showed a complete response in up to 83% of the animals treated with a low dose formulation of dual-targeting INTASYL PH-3861 (targeting PD-1 and BRD4).
  - Introduced new *in vitro* and *in vivo* data that showed silencing BRD4 with INTASYL compound PH-894 had a significant impact on T cell function and phenotype promoting T cell activation and immunosuppression in the tumor microenvironment as presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. These new data build upon a growing body of evidence that BRD4 plays a role in tumor cells and can also regulate T cell function, and that PH-894 can reprogram T cells to provide enhanced immunotherapeutic activity.
- Completed additional *in vivo* and *in vitro* preclinical studies with PH-894, an INTASYL product candidate for direct drug therapy, which showed the potential of INTASYL compounds to modulate the expression of intracellular and/or commonly considered "undruggable" targets, such as epigenetic targets. These data will support our regulatory filings and the Company expects to file a clinical trial application for PH-894 in the second half of 2022.

Upcoming Pipeline Milestones

- Expect to initiate a first-in-human clinical study on the direct therapeutic use of PH-762 in patients with advanced melanoma in the first quarter of 2022.
- Expect to initiate a first-in-human clinical study on the use of PH-762 and tumor infiltrating lymphocytes (TILs) in adoptive cell therapy (ACT) in patients with advanced melanoma in the second quarter of 2022.
- Expect to file a clinical trial application for PH-894 in the second half of 2022.
- Additional data publications on the Company's pipeline programs.

Financial Results

Cash Position

At September 30, 2021, the Company had cash of $26.5 million as compared with $14.2 million at December 31, 2020. The Company expects its current cash will be sufficient to fund currently planned operations to the second quarter of 2023.

Research and Development Expenses

Research and development expenses were approximately $2.8 million for the quarter ended September 30, 2021, compared to approximately $1.3 million for the quarter ended September 30, 2020. The increase in research and development expenses was primarily due to manufacturing costs for the Company's PH-762 and PH-894 INTASYL compounds and fees for the required preclinical studies in support of the Company's clinical trials for PH-762 as compared to the same period in the prior year.

General and Administrative Expenses

General and administrative expenses were approximately $0.9 million for the quarter ended September 30, 2021, compared to approximately $1.1 million for the quarter ended September 30, 2020. The decrease is primarily due to a decrease in legal fees partially offset by increased stock-based compensation expense as the Company did not grant equity awards in the same period in the prior year.

Net Loss

Net loss was $3.7 million, or $0.28 per share, for the quarter ended September 30, 2021, compared with $2.3 million, or $0.40 per share, for the quarter ended September 30, 2020. The increase in net loss was primarily attributable to the increase in research and development expenses related to the Company's preclinical activities in preparation for the start of its clinical trials with PH-762, as described above. The change in net loss per share was primarily due to an increase in the number of shares outstanding as a result of the Company's capital raise activities as compared to the prior year period.

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a biotechnology company developing the next generation of immuno-oncology therapeutics based on its self-delivering RNAi (INTASYL™) therapeutic platform. The Company's efforts are focused on silencing tumor-induced suppression of the immune system through its proprietary INTASYL platform with utility in immune cells and the tumor micro-environment. 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, 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, 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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 2,807	$ 1,256	$ 7,091	$ 3,253
General and administrative	932	1,050	2,970	3,078
Total operating expenses	3,739	2,306	10,061	6,331
Operating loss	(3,739)	(2,306)	(10,061)	(6,331)
Total other (expense) income	(3)	(3)	225	(1)
Net loss	$ (3,742)	$ (2,309)	$ (9,836)	$ (6,332)
Net loss per share: Basic and diluted	$ (0.28)	$ (0.40)	$ (0.78)	$ (1.51)
Weight average shares outstanding: Basic and diluted	13,534,560	5,780,386	12,593,569	4,181,862

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

	September 30, 2021	December 31, 2020
ASSETS		
Cash	$ 26,529	$ 14,244
Restricted cash	50	50
Prepaid expenses and other current assets	871	870
Right of use asset, net	313	400
Property and equipment, net	153	157
Other assets	27	18
Total assets	$ 27,943	$ 15,739
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 322	$ 728
Accrued expenses and other current liabilities	2,061	1,352
Lease liability, current	112	116
Lease liability, net of current portion	202	295
Long-term debt	–	231
Total stockholders' equity	25,246	13,017
Total liabilities and stockholders' equity	$ 27,943	$ 15,739