

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): March 22, 2022

PHIO PHARMACEUTICALS CORP.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-36304
(Commission
File Number)

45-3215903
(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 March 22, 2022, Phio Pharmaceuticals Corp. reported its financial results for the period ended December 31, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 22, 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: March 22, 2022

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



Phio Pharmaceuticals Reports 2021 Year End Financial Results and Provides Business Update

Company transitioning into a clinical stage company with start of the first clinical study for lead program, PH-762.

Marlborough, Mass., March 22, 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 year ended December 31, 2021 and provided a business update.

“Over the past year, we have made significant progress moving towards the initiation of our first-in-human clinical studies for our lead program, PH-762, in 2022. Currently, we are on track to start enrolling patients in the first of these trials, a Phase 1b study of PH-762 in advanced melanoma, in the coming weeks,” said Dr. Gerrit Dispersyn, President and CEO of Phio. “I am proud of the Phio team’s execution of our preclinical program for PH-762, which has generated a steady stream of positive data and supported our regulatory strategy. These studies were conducted during the second year of the ongoing global pandemic, which has proven to be a difficult period of time for the team, yet we incurred only minor delays to our original timelines. I believe the achievement of these milestones within the stated timeframes speak to the strength of our team and the assets in our pipeline, as well as our INTASYL platform. We look forward to continuing to deliver on our current development pipeline in 2022 as our business fulfills its transition into a clinical stage company.”

Quarter in Review and Recent Corporate Updates

- Granted clinical trial authorization (CTA) by the French National Agency for the Safety of Medicines and Health Products to proceed with a first-in-human clinical trial for PH-762 to treat patients with melanoma at the Gustave Roussy Institute, one of the largest cancer centers in Europe.
- Presented new data in an *in vivo* hepatocarcinoma model that show PH-762 administered locally cleared untreated distal tumors, which indicates a systemic immune response.
- Initiated efficacy animal studies with INTASYL-based antiviral compounds against SARS-CoV-2 infection, the virus that causes COVID-19, following collection of positive results from *in vitro* studies under this development program.

Upcoming Pipeline Milestones for 2022

- Expect to start patient enrollment 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 in the first quarter of 2022.
- Expect to initiate a first-in-human clinical study on the use of PH-762 in tumor infiltrating lymphocytes (TILs) in adoptive cell therapy (ACT) in patients with advanced melanoma in the second quarter of 2022.
- Scheduled to present new study data regarding PH-894, a BRD4-targeting, self-delivering RNAi, at the AACR Annual Meeting 2022, which is being held in New Orleans, Louisiana, from April 8-13, 2022.
- Expect to finalize IND-enabling studies for PH-894 in the second half of 2022.
- Additional data publications on the Company’s pipeline programs.

Financial Results

Cash Position

At December 31, 2021, the Company had cash of \$24.1 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 \$8.9 million for the year ended December 31, 2021, compared to approximately \$3.7 million for the year ended December 31, 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, fees for the required preclinical studies in support of the Company's clinical trials for PH-762 and CRO and consulting related costs to support the initiation of the Company's clinical trials as compared to the same period in the prior year.

General and Administrative Expenses

General and administrative expenses were approximately \$4.6 million for the year ended December 31, 2021, compared to approximately \$5.1 million for the year ended December 31, 2020. The decrease in general and administrative expenses was primarily due to a decrease in patent and legal fees partially offset by increases in the use of an outside consultant to support business development activities and corporate insurance premiums.

Net Loss

Net loss was \$13.3 million, or \$1.04 per share, for the year ended December 31, 2021, compared with \$8.8 million, or \$1.92 per share, for the year ended December 31, 2020. The increase in net loss was primarily attributable to the increase in research and development expenses related to the Company's manufacturing of its INTASYL compounds and preclinical activities in preparation for the start of its clinical trial 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 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 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.phio-pharma.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, 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.

Contact Phio Pharmaceuticals Corp.

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Investor Contact

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

	Twelve Months Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 8,886	\$ 3,716
General and administrative	4,625	5,077
Total operating expenses	13,511	8,793
Operating loss	(13,511)	(8,793)
Total other income (expense)	224	(1)
Net loss	\$ (13,287)	\$ (8,794)
Net loss per share: Basic and diluted	\$ (1.04)	\$ (1.92)
Weighted average number of common shares outstanding		
Basic and diluted	12,830,809	4,587,346

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

	December 31, 2021	December 31, 2020
ASSETS		
Cash	\$ 24,057	\$ 14,244
Restricted cash	50	50
Prepaid expenses and other current assets	620	870
Right of use asset, net	283	400
Property and equipment, net	133	157
Other assets	27	18
Total assets	<u>\$ 25,170</u>	<u>\$ 15,739</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 283	\$ 728
Accrued expenses	2,660	1,352
Lease liability	125	116
Lease liability, net of current portion	170	295
Long-term debt	-	231
Total stockholders' equity	<u>21,932</u>	<u>13,017</u>
Total liabilities and stockholders' equity	<u>\$ 25,170</u>	<u>\$ 15,739</u>