

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): May 13, 2021

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

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 May 13, 2021, Phio Pharmaceuticals Corp. reported its financial results for the period ended March 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 May 13, 2021.

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: May 13, 2021

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



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

Marlborough, Mass., May 13, 2021 -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a biotechnology company developing the next generation of immunoncology therapeutics based on its proprietary self-delivering RNAi (INTASYL™) therapeutic platform, today reported its financial results for the quarter ended March 31, 2021 and provided a business update.

"This year has started out with great momentum across our pipeline, as we continue to present a steady flow of positive data that further demonstrate the value of direct therapy with INTASYL compounds, as well as their application in improving the efficacy of cell-based immunotherapy products. Results from various animal studies, including data presented at the AACR conference last month, show how INTASYL compounds directly delivered to the tumor can activate the immune response resulting in strong anti-tumor effects. We also presented additional compelling data showing improvements of T cell immunotherapy products by reprogramming them with INTASYL compounds, and their resulting increased *in vivo* efficacy. For example, at the ASGCT conference this week, we announced data showing how PH-762 can unlock the potential of CAR-T cell therapy in solid tumors. These data provide proof-of-concept for the application of PH-762 mediated PD-1 checkpoint silencing in CAR-T cells prior to adoptive cell therapy to enhance the therapeutic efficacy of CAR-T cell therapy. This is tremendous data for our program, especially when considering a recently published clinical study showing that similar strategies using CRISPR-Cas9 mediated PD-1 disruption in T cells is much less efficient," said Dr. Gerrit Dispersyn, President and CEO of Phio.

"As a result of the overwhelmingly positive data we've collected across our pipeline, we have moved to initiate a clinical study using intra-tumoral administration of PH-762 in patients with advanced melanoma, which is expected to begin in the fourth quarter of 2021. The clinical trial will be conducted at the Gustave Roussy Institute, which is one of the leading anti-cancer centers in Europe, with Dr. Caroline Robert as our lead principal investigator. This is an exciting next step in the development of innovative therapeutics based on our INTASYL platform and we look forward to keeping you posted as we move closer towards initiation of the study," concluded Dr. Dispersyn.

Quarter in Review and Recent Corporate Updates

- Presented positive data from a study assessing the potential of PH-762, a PD-1 targeting INTASYL compound, to enhance the therapeutic efficacy of HER2-targeted CAR-T cells (HER2CART) in solid tumors, namely a subcutaneous HER2-expressing SKOV3 model of human ovarian cancer in mice. Compared to untreated HER2CART cells, HER2CART cells treated with PH-762 showed a statistically significant and durable inhibition of *in vivo* tumor growth. These data were included in a poster presentation during the 24th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT).
- Announced new *in vivo* data showing intratumoral (IT) treatment with PD-1 targeting INTASYL (mPH-762) inhibits tumor growth in a dose dependent fashion in both PD-1 responsive and refractory models. These data were included in a poster presentation during the American Association for Cancer Research (AACR) Annual Meeting 2021.

- Further bolstered the balance sheet to a total of \$32.7 million in cash, following the completion of two financings in Q1 2021 for gross proceeds of \$21.7 million in additional capital.
 - o Completed a \$7.7 million registered direct offering of common stock priced at-the-market.
 - o Completed a \$14.0 million private placement of common stock and warrants priced at-the-market.

Upcoming Pipeline Milestones for 2021

- Scheduled to present new *in-vivo* data regarding dual targeting INTASYL drug therapy (BRD4 and PD-1) at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.
- Initiate a first-in-human clinical study on the use of PH-762 in adoptive cell therapy with tumor infiltrating lymphocytes in patients with metastatic melanoma or squamous cell carcinoma of the head and neck (SSCHN).
- Initiate a first-in-human clinical study on the use of PH-762 direct drug therapy (intratumoral injection) in patients with advanced melanoma.
- Additional data publications on the Company's pipeline programs.

Financial Results

Cash Position

At March 31, 2021, the Company had cash of \$32.7 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 \$2.6 million for the quarter ended March 31, 2021, compared to approximately \$1.2 million for the quarter ended March 31, 2020. The increase is primarily due to manufacturing costs and fees for the required preclinical studies in support of the Company's planned 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 \$1.0 million for the quarter ended March 31, 2021, compared to approximately \$1.1 million for the quarter ended March 31, 2020. The decrease is primarily due to a decrease in legal fees as compared to the same period in the prior year.

Net Loss

Net loss was \$3.4 million, or \$0.32 per share, for the quarter ended March 31, 2021, compared with \$2.4 million, or \$1.33 per share, for the quarter ended March 31, 2020. The increase in net loss was primarily attributable to the increase in research and development expenses, 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.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 are neither historical facts nor assurances of future performance. These statements are based only on our current beliefs, expectations and assumptions regarding the impact to our business and operations by the recent coronavirus outbreak, results from our preclinical and clinical activities, the development of our product candidates, the ability to obtain future financing, 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, 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 2,621	\$ 1,218
General and administrative	1,017	1,138
Total operating expenses	3,638	2,356
Operating loss	(3,638)	(2,356)
Other income (expense)		
Gain on extinguishment of debt	233	-
Interest (expense) income, net	(2)	5
Total other income	231	5
Net loss	\$ (3,407)	\$ (2,351)
Net loss per common share:		
Basic and diluted	\$ (0.32)	\$ (1.33)
Weighted average number of common shares outstanding		
Basic and diluted	10,680,395	1,772,970

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

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current assets:		
Cash	\$ 32,695	\$ 14,244
Restricted cash	50	50
Prepaid expenses and other current assets	577	870
Total current assets	33,322	15,164
Right of use asset, net	371	400
Property and equipment, net	145	157
Other assets	18	18
Total assets	<u>\$ 33,856</u>	<u>\$ 15,739</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 615	\$ 728
Accrued expenses and other current liabilities	1,458	1,352
Lease liability	118	116
Total current liabilities	2,191	2,196
Lease liability, net of current portion	265	295
Long-term debt	–	231
Total liabilities	2,456	2,722
Total stockholders' equity	31,400	13,017
Total liabilities and stockholders' equity	<u>\$ 33,856</u>	<u>\$ 15,739</u>