

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 12, 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 August 12, 2021, Phio Pharmaceuticals Corp. reported its financial results for the period ended June 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 12, 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: August 12, 2021

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



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

Marlborough, Mass., August 12, 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 June 30, 2021 and provided a business update.

“The first half of 2021 was just the start of what promises to be an exciting period in our development of the INTASYL™ enabled immunotherapy compounds across our pipeline. Over the past several months, we have generated positive new preclinical data from different studies that support the initiation of two first-in-human studies of our lead asset PH-762, an INTASYL compound that targets the checkpoint protein PD-1, in cancer patients. Looking ahead, we are finalizing the studies required for the regulatory submissions for each program and expect to be in a position to initiate both studies in the first half of 2022,” said Dr. Gerrit Dispersyn, President and CEO of Phio. “Overall, we are very excited by the overwhelmingly positive data generated by our pipeline of INTASYL based product candidates. This data shows that the INTASYL platform is a valuable alternative to other direct therapeutic approaches, but can also be used to improve cell based immunotherapy products.”

Quarter in Review and Recent Corporate Updates

- Presented a continuous stream of positive data from preclinical studies exploring the flexibility and application of INTASYL in the field of immuno-oncology at leading scientific conferences held during the second quarter of 2021:
 - Announced positive new data at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting that provide further evidence on the utility of the INTASYL self-delivering RNAi therapy platform to target multiple proteins and provide evidence of the synergy of the Company's pipeline products in the field of immuno-oncology. These *in vivo* data showed that INTASYL specifically dual-targeting BRD4 and PD-1 elicited complete tumor responses in an *in vivo* hepatoma model, and significantly outperformed the efficacy of small molecule and antibody treatments towards the same targets.
 - Announced positive *in vivo* data at the 24th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT) showing that PH-762 can reprogram HER2-targeted CAR-T cells (HER2CART) and significantly enhance their antitumor efficacy in solid tumors, compared to untreated HER2CART cells.
 - Announced new *in vivo* data at the American Association for Cancer Research (AACR) Annual Meeting 2021 showing that 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.

Upcoming Pipeline Milestones

- Expect to initiate a first-in-human clinical study on the use of PH-762 using direct drug therapy (IT) administration for 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.
- Additional data publications on the Company's pipeline programs.

Financial Results

Cash Position

At June 30, 2021, the Company had cash of \$29.4 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 \$1.7 million for the quarter ended June 30, 2021, compared to approximately \$0.8 million for the quarter ended June 30, 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. The Company expects its research and development expenses to continue to increase in support of, and as the Company commences its clinical trial activities with PH-762.

General and Administrative Expenses

General and administrative expenses were approximately \$1.0 million for the quarter ended June 30, 2021, compared to approximately \$0.9 million for the quarter ended June 30, 2020. The increase is primarily due to an increase in stock-based compensation expense as no equity awards were granted in the prior year period.

Net Loss

Net loss was \$2.7 million, or \$0.20 per share, for the quarter ended June 30, 2021, compared with \$1.7 million, or \$0.34 per share, for the quarter ended June 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.phiotherapeutics.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 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, 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.

ir@phiopharma.com

Investor Contact

Ashley R. Robinson

LifeSci Advisors

arr@lifesciadvisors.com

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 1,663	\$ 779	\$ 4,284	\$ 1,997
General and administrative	1,021	890	2,038	2,028
Total operating expenses	<u>2,684</u>	<u>1,669</u>	<u>6,322</u>	<u>4,025</u>
Operating loss	(2,684)	(1,669)	(6,322)	(4,025)
Total other (expense) income	(3)	(3)	228	2
Net loss	<u>\$ (2,687)</u>	<u>\$ (1,672)</u>	<u>\$ (6,094)</u>	<u>\$ (4,023)</u>
Net loss per share: Basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.34)</u>	<u>\$ (0.50)</u>	<u>\$ (1.19)</u>
Weighted average shares outstanding: Basic and diluted	<u>13,534,389</u>	<u>4,966,047</u>	<u>12,115,276</u>	<u>3,378,233</u>

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

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
ASSETS		
Cash	\$ 29,425	\$ 14,244
Restricted cash	50	50
Prepaid expenses and other current assets	1,680	870
Right of use asset, net	342	400
Property and equipment, net	142	157
Other assets	18	18
Total assets	<u>\$ 31,657</u>	<u>\$ 15,739</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 348	\$ 728
Accrued expenses and other current liabilities	2,110	1,352
Lease liability, current	120	116
Lease liability, net of current portion	234	295
Long-term debt	–	231
Total stockholders' equity	28,845	13,017
Total liabilities and stockholders' equity	<u>\$ 31,657</u>	<u>\$ 15,739</u>