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

May 12, 2022

First-in-human clinical study of PH-762 for the treatment of advanced melanoma open for enrollment

Expect to finalize IND-enabling studies for PH-894 in the second half of 2022

MARLBOROUGH, Mass., May 12, 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 March 31, 2022 and provided a business update.

Logo - https://mma.prnewswire.com/media/786567/Phio_Pharmaceuticals_Logo.jpg

"We are pleased enrollment is open for our first-in-human clinical trial for PH-762 at the Gustave Roussy Institute, one of the largest cancer centers in Europe. This study will evaluate the safety, tolerability, pharmacokinetics and checkpoint anti-tumor activity of PH-762 in a neoadjuvant setting in subjects with advanced melanoma. The clinical 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. "In addition, the new preclinical data we recently presented at the AACR Annual Meeting shows the potential of PH-894 to be used in treating patients who do not respond to anti-PD-1 therapy, or patients who progress after initially responding to treatment with checkpoint inhibitors. The reaction of the investment community when this data was presented, reinforces the relevance of a compound like PH-894, an INTASYL compound specifically targeting BRD4, in patients who may not respond or relapse after PD-1 therapy. We expect to finalize IND-enabling studies for PH-894 in the second half of 2022," concluded Dr. Cauwenbergh.

Quarter in Review and Recent Corporate Updates

- Enrollment open for the Company's 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 *in vivo* data at the AACR Annual Meeting 2022 that provide a strong rationale for the clinical use of PH-894, a BRD4-targeting, self-delivering RNAi, as a monotherapy, as well as in combination with systemic PD-1 therapy.
- Continue to develop PH-3861, a dual-targeting INTASYL towards PD-1 and BRD4. Last year this program reported data that show PH-3861 elicited complete cure of tumors in an *in vivo* hepatoma model and outperformed the efficacy of the small molecule and antibody control treatments toward the same targets. In addition, local INTASYL therapy was shown to induce a systemic anti-tumor response with clearance of untreated distal tumors.

Upcoming Pipeline Milestones

- Expect to finalize IND-enabling studies for PH-894 in the second half of 2022.
- On track to report top-line data from the first group of patients 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 March 31, 2022, the Company had cash of $20.5 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 second quarter of 2023.

Research and Development Expenses

Research and development expenses were approximately $1.6 million for the quarter ended March 31, 2022, compared with approximately $2.4 million for the quarter ended March 31, 2021. The decrease was primarily due to the preclinical studies and manufacturing costs to support the Company's clinical trial with PH-762, which were completed in the prior year period, offset by increases in CRO costs in preparation for the start of the Company's clinical trial with PH-762 and personnel-related expenses due to an increase in headcount as compared to the prior year period.

General and Administrative Expenses

General and administrative expenses were approximately $1.1 million for the quarter ended March 31, 2022, compared with approximately $1.2 million for the quarter ended March 31, 2021. The decrease was primarily due to decreases in legal and patent fees offset by an increase in stock-based compensation expense.

Net Loss

Net loss was $2.6 million, or $0.19 per share, for the quarter ended March 31, 2022, compared with $3.4 million, or $0.32 per share, for the quarter ended March 31, 2021. The decrease in net loss was primarily attributable to the decrease in research and development expenses as described above.

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, 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.
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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 1,586	$ 2,429
General and administrative	1,054	1,209
Total operating expenses	2,640	3,638
Operating loss	(2,640)	(3,638)
Total other (expense) income	(2)	231
Net loss	$ (2,642)	$ (3,407)
Net loss per share: Basic and diluted	$ (0.19)	$ (0.32)
Weighted average number of common shares outstanding Basic and diluted	13,564,129	10,680,395

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

	March 31, 2022	December 31, 2021
ASSETS		
Cash	$ 20,459	$ 24,057
Restricted cash	50	50
Prepaid expenses	1,158	620
Right of use asset, net	253	283

Property and equipment, net	215	133
Other assets	27	27
Total assets	$ 22,162	$ 25,170
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 329	$ 283
Accrued expenses	2,117	2,660
Lease liability	265	295
Total stockholders' equity	19,451	21,932
Total liabilities and stockholders' equity	$ 22,162	$ 25,170

View original content:https://www.prnewswire.com/news-releases/phio-pharmaceuticals-reports-first-quarter-2022-financial-results-and-provides-business-update-301546581.html

SOURCE Phio Pharmaceuticals Corp.