Phio Pharmaceuticals Reports 2022 Year End Financial Results and Provides Business Update

- Following safety data review by the DMC, enrollment is now open for the second cohort of its Phase 1b study of PH-762 for the treatment of advanced melanoma -

- Received confirmation from the FDA that the planned Phase 1 clinical trial in patients with advanced solid tumors, in collaboration with Phio's development partner AgonOx, may proceed -

- Newly integrated management and clinical teams continue to make significant advancements across the Company's development programs -

MARLBOROUGH, Mass., March 22, 2023 /PRNewswire/ -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a clinical stage biotechnology company whose proprietary INTASYL™ RNAi platform technology is designed to make immune cells more effective in killing tumor cells, today reported its financial results for the year ended December 31, 2022 and provided a business update.

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

"This year will be a transformative period for Phio, as we continue to make significant progress advancing our proprietary platform, INTASYL, into the clinic," said Robert Bitterman, Phio's President and Chief Executive Officer. "We are completely focused on executing our clinical strategy for PH-762. Over the past several months we have achieved several key milestones, including completing enrollment of the first cohort in our Phase 1b study for PH-762 in Europe, receiving Data Monitoring Committee (DMC) approval to open enrollment of the second cohort and receiving regulatory clearance to initiate the first U.S. clinical trial for PH-762 in adoptive cell therapy. Simultaneously, we are preparing to finalize documentation to submit an IND for PH-762 for the study of cutaneous squamous cell carcinoma and other cutaneous malignancies. We look forward to continuing to provide updates on these programs over the coming months as we strive to build shareholder value."

Recent Corporate Updates

- In February 2023, the Company announced an independent DMC completed its prespecified review of interim safety data in the Company's ongoing Phase 1b clinical trial (EU) of PH-762, an INTASYL compound targeting PD-1, for the treatment of advanced melanoma, which is being conducted at the Gustave Roussy Institute (Villejuif, France). The safety data review disclosed no dose-limiting toxicity, and no drug-related severe adverse events or serious adverse events, and the DMC recommended proceeding to the enrollment of the subsequent dose cohort, as intended per the study protocol.
- In the first quarter of 2023, following the recommendation by the DMC, the Company opened enrollment of subjects in the second cohort of the ongoing Phase 1b dose escalation clinical trial (EU) of PH-762 for the treatment of advanced melanoma.
- In January 2023, the Company announced its partner AgonOx, Inc. received confirmation from the FDA to proceed with the planned Phase 1 clinical trial in adoptive cell therapy (ACT) designed to assess safety and to study the potential for an enhanced therapeutic benefit from the administration of Phio's PH-762 treated "double positive" (DP) CD8 tumor infiltrating lymphocyte (TIL) in patients with melanoma and other advanced solid tumors.
- The Company has completed the IND-enabling studies for PH-894 and is in the process of finalizing the study reports required for an IND submission with PH-894.
- In February 2023, the Company received a letter from The Nasdaq Stock Market LLC advising the Company that

it had regained compliance with Nasdaq's minimum bid price listing requirements following the implementation of a one-for-twelve reverse split of the Company's common stock. Nasdaq advised that the matter was closed as Phio satisfied all criteria for continued listing.
- The Board of Directors recently appointed Robert Bitterman as the Company's President and Chief Executive Officer. Mr. Bitterman had previously served as Interim Chief Executive Officer of the Company since September 2022. Mr. Bitterman continues to serve as Chair of the Board, and as the Company's principal executive officer and principal financial officer.

Upcoming Pipeline Milestones

- Plan to commence a U.S. Phase 1b clinical trial with PH-762 focused on the treatment of cutaneous squamous cell carcinoma ("cSCC") and other selected cutaneous malignancies in the second half of 2023.
- In partnership with AgonOx, Inc., plan to commence enrollment of subjects in a clinical trial evaluating the use of PH-762 and DP TIL in ACT during the second quarter of 2023.
- Additional data publications on the Company's pipeline programs.

Financial Results

Cash Position

At December 31, 2022, the Company had cash of $11.8 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 through the fourth quarter of 2023.

Research and Development Expenses

Research and development expenses decreased 21% to approximately $7.0 million for the year ended December 31, 2022 compared with approximately $8.9 million for the year ended December 31, 2021. The decrease in research and development expenses was primarily driven by manufacturing related costs for the Company's PH-762 and PH-894 compounds and the preclinical studies with PH-762 - both of which were completed in the prior year period - that were offset by increases in clinical-related costs for the Company's ongoing clinical trials with PH-762 in France and in ACT with our partner, AgonOx.

General and Administrative Expenses

General and administrative expenses decreased 4% to approximately $4.5 million for the year ended December 31, 2022 compared with approximately $4.6 million for the year ended December 31, 2021. The decrease in general and administrative expenses was primarily due to decreases in total payroll-related expenses as a result of the departure of the Company's former Chief Executive Officer and a reduction in the use of consultants and outside professional services, which were offset by executive search fees in 2022.

Net Loss

Net loss decreased 14% to approximately $11.5 million, or $10.10 per share, for the year ended December 31, 2022, compared with $13.3 million, or $12.43 per share, for the year ended December 31, 2021. The decrease in net loss was primarily attributable to the decrease in research and development expenses as described above.

About INTASYL

INTASYL compounds are chemically modified siRNAs that provide efficient, spontaneous cellular uptake and potent, long lasting intracellular activity, targeting a broad range of cell types and tissues. INTASYL drugs precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems. INTASYL has demonstrated preclinical efficacy in both Direct-to-Tumor and Adoptive Cell Therapy

(ACT) applications.

In comparison to biologics and cell and gene therapies, INTASYL has a favorable pre-clinical toxicity and safety profile, and a streamlined chemical synthesis that reduces costs and offers substantial dosing convenience to the prescriber and patient. INTASYL is the only self-delivering RNA interference (RNAi) technology focused on immuno-oncology therapeutics.

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a clinical stage biotechnology company whose proprietary INTASYL™ RNAi technology is designed to make immune cells more effective in killing tumor cells. INTASYL is the only self-delivering RNAi technology focused on immuno-oncology therapeutics. INTASYL drugs precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems.

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. These statements are based only on our current beliefs, expectations and assumptions and 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, military conflict between Ukraine and Russia, inflationary pressures, rising interest rates, recession fears, 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.

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

	Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 7,012	$ 8,886
General and administrative	4,450	4,625
Total operating expenses	11,462	13,511
Operating loss	(11,462)	(13,511)
Total other (expense) income, net	(18)	224
Net loss	$ (11,480)	$ (13,287)
Net loss per common share:		
Basic	$ (10.10)	$ (12.43)
Diluted	$ (10.10)	$ (12.43)
Weighted average number of common shares outstanding		
Basic	1,136,566	1,069,234
Diluted	1,136,566	1,069,234

PHIO PHARMACEUTICALS CORP.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share data)

	December 31, 2022	**December 31, 2021**
ASSETS		
Cash	$ 11,781	$ 24,057
Restricted cash	50	50
Prepaid expenses and other current assets	615	620
Right of use asset	161	283
Property and equipment, net	183	133
Other assets	24	27
Total assets	$ 12,814	$ 25,170
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 779	$ 283
Accrued expenses	1,025	2,660
Lease liability	170	295
Total preferred stock	2	-
Total stockholders' equity	10,838	21,932
Total liabilities, preferred stock and stockholders' equity	$ 12,814	$ 25,170

SOURCE Phio Pharmaceuticals Corp.