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): December 21, 2022

PHIO PHARMACEUTICALS CORP.

(Exact name of registrant as specified in its charter)

Delaware	001-36304	45-3215903
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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 8.01 Other Events.

On December 21, 2022, Phio Pharmaceuticals Corp. (the "Company") issued a press release announcing that the Company expects to file an investigational new drug application with the U.S. Food and Drug Administration for a Phase 1b clinical trial pertaining to the Company's INTASYL compound, PH-762, which is expected to be conducted in the United States during the first half of 2023. The full text of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press Release dated December 21, 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: December 21, 2022

By: /s/ Robert Bitterman
Name: Robert Bitterman
Title: Interim Executive Chairman

Exhibit 99.1

Phio Pharmaceuticals Announces New Clinical Program to Study PH-762 for the Treatment of Cutaneous Squamous Cell Carcinoma

Marlborough, Mass., December 21, 2022/PR Newswire/-- Phio Pharmaceuticals Corp., today announced it expects to file an IND in the US in the first half of 2023 for a Phase 1b clinical trial of its INTASYL™ compound, PH-762. Phio is a clinical stage biotechnology company whose proprietary INTASYL self-delivering RNAi technology is designed to make immune cells more effective in killing tumor cells. PH-762 has been shown to reduce the expression of PD-1, a protein that inhibits T cells' ability to kill cancer cells. When administered intratumorally in preclinical models PH-762 primes an anti-tumor immune response, and inhibits tumor growth.

Phio is currently conducting a Phase 1b clinical trial of PH-762 for the treatment of advanced melanoma at the Gustave Roussy Institute, one of the largest cancer centers in Europe. Phio expects to commence a US Phase 1b clinical trial early in the 2nd half of 2023. The initial US trial is expected to focus on the treatment of cutaneous squamous cell carcinoma (cSCC) and other selected cutaneous malignancies, following successful regulatory review of the IND.

"Therapeutic interventions for cSCC are limited, and there is increasing unmet medical need. As cSCC tumors comprise approximately 51% of the total incidence of solid tumors in the US, excluding basal cell cancers, we recognize the growing need for alternative therapies for cSCC," said Robert Bitterman, Phio's Principal Executive Officer and Executive Chairman. Mr. Bitterman has over 25 years of executive leadership experience in the pharmaceutical and biologic life science industry with a proven track record in operations, finance and investor relations.

"While monoclonal antibody therapies (mAbs) are available for the treatment of cSCC, mechanistically they only block the interaction between PD-1 and PD-L1 on the cell surface. PH-762 also has the potential to address PD-1 inside the T cell, essentially further enhancing the activity of the T cell to kill the tumor cells," said Dr. James Cardia, Phio's Vice President of Scientific Operations. Dr. Cardia led the team that discovered INTASYL.

"PH-762 has the potential to meet a significant medical need in patients who have failed to respond to mAbs, as well as those with resectable and metastatic solid tumors," noted Dr. Mary Spellman, Phio's Medical and Clinical Development Advisor. "Phio is committed to advancing the study of PH-762 to provide a meaningful therapy for patients with a broad range of solid tumors."

About INTASYL

INTASYL compounds are chemically modified siRNAs that are designed to 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 convenience to the prescriber and patient. Phio believes that INTASYL is the only self-delivering RNA interference (RNAi) technology focused on immuno-oncology therapeutics.

About Phio Pharmaceuticals

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. Phio believes that 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. Forward-looking statements are neither historical facts nor assurances of future performance and include statements regarding the anticipated timing of our PH-762 IND application and subsequent Phase 1b clinical trial, the clinical focus of the anticipated Phase 1b clinical trial, and the anticipated results of such clinical trial. 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, 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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