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PHIO PHARMACEUTICALS CORP.

FORM 8-K
(Current report filing)

Filed 11/23/26 for the Period Ending 11/23/26

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Telephone	(508) 767-3861
CIK	0001533040
Symbol	PHIO
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): November 23, 2026

PHIO PHARMACEUTICALS CORP.
(Exact name of registrant as specified in its charter)

Delaware	**001-36304**	**45-3215903**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

411 Swedeland Road, Suite 23-1080 **King of Prussia, PA**	**19406**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(610) 947-0251**

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:	Trading Symbol(s):	Name of each exchange on which registered:
Common Stock, par value $0.0001 per share	**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 8.01. Other Events.

On November 23, 2026, the Company announced that it received written feedback from the U.S. Food and Drug Administration ("FDA") in response to the Company's Type C meeting request regarding the development program for PH-762. The FDA indicated that key components of the Company's nonclinical and clinical pharmacology strategy appear reasonable to support continued development and a future marketing application, subject to final review. The Company remains on track to initiate its planned randomized, placebo-controlled Phase 2b study of PH-762 in the first quarter of 2027.

The full text of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Forward-Looking Statements

This Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “continue” and similar words. Such statements are only predictions and actual events or results may differ materially from those anticipated in these forward-looking statements. You should not place undue reliance on any forward-looking statements. The Company does not assume any obligation to update forward-looking statements as circumstances change, except as required by securities laws.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on November 23, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PHIO PHARMACEUTICALS CORP.

Date: November 23, 2026

By: /s/ Robert J. Bitterman
Robert J. Bitterman
President & Chief Executive Officer

Phio Receives Written Guidance from FDA Supporting Continued Advancement of PH-762; Remains on Track for Randomized Phase 2b Study in Q1 2027

KING OF PRUSSIA, PA, November 23, 2026 (NEWSFILE) — Phio Pharmaceuticals Corp. (NASDAQ: PHIO) is a clinical-stage siRNA biopharmaceutical company developing therapeutics using its proprietary INTASYL® gene silencing technology to eliminate cancer. Phio today announced significant progress in the development of its lead clinical-stage immunotherapy candidate, PH-762. U.S. Food and Drug Administration (FDA) written feedback was received in response to Phio's Type C meeting request seeking guidance regarding the Phase 2b development program and future registration pathway.

The FDA indicated that the Company's overall non-clinical package appears reasonable to support a future marketing application, subject to final review. The FDA accepted Phio's proposed weight-of-evidence approach for reproductive risk assessment and provided feedback that local tumor activity can be considered a primary efficacy driver. The FDA also provided recommendations to enhance the Company's clinical pharmacology to support continued development.

The Company believes this feedback may reduce the need for additional nonclinical studies prior to filing a New Drug Application (NDA) for PH-762.

The Company's planned randomized, placebo-controlled Phase 2b study remains focused on evaluating PH-762 as a neoadjuvant treatment for cutaneous squamous cell carcinoma (cSCC), building upon previously reported clinical results that demonstrated a 65% overall pathologic response rate and a 45% pathologic complete response rate among evaluable cSCC patients treated with PH-762. The Company remains on track to initiate a randomized placebo-controlled Phase 2b study in the first quarter of 2027.

"We believe this FDA interaction represents an important step in de-risking the advancement of the PH-762 program and provides valuable guidance as we prepare for our planned Phase 2b study," said Robert Bitterman, President and Chief Executive Officer of Phio Pharmaceuticals. "Importantly, the FDA characterized our overall nonclinical package as appearing reasonable to support a future marketing application and indicated that our proposed genetic toxicity strategy appears sufficient. We believe these responses provide a clear framework for advancing PH-762 while further strengthening the clinical, pharmacologic, and regulatory foundation of the program. We are focused on incorporating FDA feedback into our development strategy and advancing our planned randomized placebo-controlled Phase 2b trial."

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a clinical-stage biopharmaceutical company advancing its proprietary INTASYL® siRNA gene silencing technology to eliminate cancer. Phio's INTASYL compounds are designed to enhance the body's immune cells to more effectively kill cancer cells. Phio's lead clinical development program is an INTASYL compound, PH-762, that silences the PD-1 gene implicated in various forms of skin cancer. The Phase 1b trial (NCT# 06014086) evaluated PH-762 for the treatment of cutaneous squamous cell carcinoma, melanoma and Merkel cell carcinoma. PH-762 is a potential non-surgical treatment for skin cancers.

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, which include statements, among other things, regarding the possibility that our INTASYL® siRNA gene silencing technology will make the body's immune cells more effective in killing cancer cells, our expectations with respect to the FDA's guidance regarding the written responses to our Type C meeting request, including that key components of our non-clinical and clinical pharmacology study appear reasonable to support continued development and a future marketing application, subject to final review, our belief that the FDA's feedback may reduce the need for additional nonclinical studies prior to filing a potential NDA for PH-762, , and our expectation that a Phase 2b study will be initiated in the first quarter of 2027, 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 of future FDA interactions on the development of our product candidates; the impact to our business and operations by inflationary pressures; recession fears; the development of our product candidates, results from our nonclinical, 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 risks identified in our most recent 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 U.S. Securities and Exchange Commission. 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:

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Corporate Affairs