
**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): October 23, 2020

PhaseBio Pharmaceuticals, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-38697
(Commission
File Number)

03-0375697
(IRS Employer
Identification No.)

1 Great Valley Parkway, Suite 30
Malvern, Pennsylvania
(Address of Principal Executive Offices)

19355
(Zip Code)

(610) 981-6500
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 Instructions 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 exchange on which registered
Common Stock	PHAS	The Nasdaq Stock Market LLC

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 October 23, 2020, PhaseBio Pharmaceuticals, Inc. issued a press release entitled "PhaseBio Provides Pemziviaptadil (PB1046) Program Update." The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 23, 2020.

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.

PhaseBio Pharmaceuticals, Inc.

Dated: October 23, 2020

By: /s/ John P. Sharp
John P. Sharp
Chief Financial Officer



PhaseBio Provides Pemziviaptadil (PB1046) Program Update

VANGARD trial discontinued due to evolving COVID-19 treatment landscape, recent feedback from FDA regarding regulatory and development path, and interim analysis of trial data

Enrollment expected to resume for ongoing Phase 2b trial of pemziviaptadil in pulmonary arterial hypertension (PAH)

Malvern, PA and San Diego, CA - October 23, 2020 - PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today announced that, after a strategic review of the VANGARD clinical trial that included an assessment of the evolving COVID-19 treatment landscape, feedback from the U.S. Food and Drug Administration (FDA) and an interim analysis of the VANGARD study data, it has elected to discontinue the trial. Importantly, pemziviaptadil was generally well tolerated and there was no adverse safety signal reported in the VANGARD trial.

In response to the medical community's rapidly evolving understanding of COVID-19 disease progression and approaches to treatment, PhaseBio recently submitted a revised VANGARD trial protocol and received feedback from the FDA regarding the regulatory and development path in COVID-related ARDS. For pemziviaptadil use in hospitalized COVID-19 patients at high risk for rapid clinical deterioration and ARDS, the FDA highlighted the likely need for additional clinical trials with sufficient sample size to adequately assess mortality risk. Based on this feedback, PhaseBio determined that it would be unlikely that the 70 patients targeted for enrollment in each of the VANGARD trial's treatment arms would be sufficient in size to adequately evaluate mortality and that at least one additional clinical trial with a mortality endpoint, which would require significantly more patients, would be required for approval of pemziviaptadil for use in patients diagnosed with COVID-19.

PhaseBio also elected to accelerate the timeline for its previously planned interim analysis. Based upon its analysis of the first 25 patients enrolled in the VANGARD trial, PhaseBio did not observe any data trends in the 40 mg or 100 mg pemziviaptadil-treated arms of the trial that suggested a reasonable probability of achieving the primary efficacy endpoint; however, data from a larger number of patients would be necessary to draw a definitive conclusion. Pemziviaptadil was generally well tolerated, and an independent data safety monitoring board did not identify any safety concerns related to pemziviaptadil.

"While extremely difficult to make, our decision to discontinue the VANGARD trial came after a review of the rapidly evolving COVID-19 treatment landscape, the changing regulatory path, the results of the interim data analysis and the potential benefit to patients of advancing this program versus deploying our resources to other studies," said Jonathan Mow, Chief Executive Officer, PhaseBio Pharmaceuticals. "We would like to thank the patients who participated in the VANGARD trial, the trial investigators and the PhaseBio team, who worked tirelessly to rapidly design and launch the trial during a global pandemic. We remain committed to moving our broader pipeline forward, fulfilling our strategic objectives and delivering new treatment options for patients with serious cardiovascular diseases."

The ongoing Phase 2b trial of pemziviaptadil in patients with PAH, named the VIP Trial (**V**asoactive **I**ntestinal **P**eptide in adult patients with pulmonary arterial hypertension) is expected to quickly resume enrollment after a pause related to the impacts of the COVID-19 pandemic and re-prioritization of drug supply to the VANGARD trial. To date, approximately one third of the patients targeted for enrollment have completed the initial 16 week protocol, with approximately 90% of these patients electing to enroll in VIP EXTEND (Vasoactive Intestinal Peptide extension trial in adult patients with pulmonary arterial hypertension), the open label extension of the Phase 2b trial. Results from the VIP Trial are expected to be reported in the second half of 2021.

About Pemziviaptadil (PB1046)

Pemziviaptadil, a novel, subcutaneously-injected vasoactive intestinal peptide (VIP) analogue, is a recombinant fusion protein composed of VIP and PhaseBio's proprietary elastin-like polypeptide (ELP) biopolymer. Based on the pharmacokinetic profile of pemziviaptadil observed in clinical trials, the fusion of VIP to ELP results in both a prolonged absorption profile and a longer circulating half-life, enabling once-weekly dosing.

Pemziviaptadil is in Phase 2 development for the treatment of pulmonary arterial hypertension (PAH). PhaseBio expects to report initial data from the Phase 2b trial in PAH in the second half of 2021. To date, pemziviaptadil has been administered to more than 100 patients with cardiovascular or cardiopulmonary diseases in five clinical trials conducted in the United States. The FDA has granted pemziviaptadil orphan drug designation for the treatment of pulmonary arterial hypertension (WHO Group 1 Pulmonary Hypertension) and cardiomyopathy associated with dystrophinopathies.

About PhaseBio Pharmaceuticals

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiovascular and cardiopulmonary diseases. The company's pipeline includes: bentracimab (PB2452), a novel reversal agent for the antiplatelet therapy ticagrelor; pemziviaptadil (PB1046), a once-weekly vasoactive intestinal peptide receptor agonist for the treatment of pulmonary arterial hypertension; and PB6440, an oral agent for the treatment of resistant hypertension. PhaseBio's proprietary elastin-like polypeptide technology platform enables the development of therapies with potential for less-frequent dosing and improved pharmacokinetics, including pemziviaptadil, and drives both internal and partnership drug-development opportunities.

PhaseBio is located in Malvern, PA, and San Diego, CA. For more information, please visit www.phasebio.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying the conduct or timing of our Phase 2b trial of pemziviaptadil for the treatment of pulmonary arterial hypertension, including the expected timing for resuming enrollment and reporting results from such trial, or other product candidates in our pipeline, our research, development and regulatory plans for our product candidates, the potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed and marketed. Forward-

looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. Such risks may be amplified by the impacts of the COVID-19 pandemic. These forward-looking statements speak only as of the date hereof, and PhaseBio Pharmaceuticals, Inc. disclaims any obligation to update these statements except as may be required by law.

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