# 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): April 8, 2019**

# PhaseBio Pharmaceuticals, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-38697** | **03-0375697** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **1 Great Valley Parkway, Suite 30**<br>**Malvern, Pennsylvania** | **19355** |
| **(Address of Principal Executive Offices)** | **(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))

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 7.01 Regulation FD Disclosure.**

On April 8, 2019, PhaseBio Pharmaceuticals, Inc. (the "***Company***") issued a press release announcing that the United States Food and Drug Administration has granted breakthrough therapy designation for PB2452 for the reversal of the antiplatelet activity of ticagrelor. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated April 8, 2019, titled "PhaseBio Receives FDA Breakthrough Therapy Designation for PB2452 for the Reversal of the Antiplatelet Activity of Ticagrelor." |

**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: April 8, 2019

By: /s/ John Sharp
John Sharp
*Chief Financial Officer*

**Exhibit 99.1**

**PhaseBio Receives FDA Breakthrough Therapy Designation for PB2452 for the Reversal of the Antiplatelet Activity of Ticagrelor**

*In Phase 1 clinical trial, PB2452 provided immediate and sustained reversal of ticagrelor antiplatelet effects*

**Malvern, PA, and San Diego, CA, April 8, 2019** — PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for orphan diseases, today announced that the U.S. Food and Drug Administration ("FDA") has granted Breakthrough Therapy designation for PB2452, a novel reversal agent for the antiplatelet drug ticagrelor.

Breakthrough Therapy designation is designed to expedite the development and review of promising new drugs for serious or life-threatening conditions, when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. With all the features of the Fast Track program, Breakthrough Therapy designation also offers companies the opportunity for increased communication with FDA and an organizational commitment involving more intensive guidance from FDA senior managers. Companies may also be eligible for Accelerated Approval and Priority Review, if relevant criteria are met.

The Breakthrough Therapy designation for PB2452 was supported by Phase 1 trial results, in which PB2452 achieved immediate and sustained reversal of ticagrelor's antiplatelet effects. The results from this trial were recently published in the New England Journal of Medicine and presented in a featured clinical research session at the American College of Cardiology's 68th Scientific Session (ACC.19).

"Breakthrough Therapy designation for PB2452 highlights the critical unmet need for a therapy to reverse the antiplatelet activity of ticagrelor, which is widely prescribed to patients with acute coronary syndrome or a history of heart attack," said John Lee, M.D., Chief Medical Officer of PhaseBio. "The results from the Phase 1 clinical trial of PB2452 demonstrated immediate and sustained reversal of the antiplatelet activity of ticagrelor, which could mitigate bleeding concerns associated with use of ticagrelor. Breakthrough Therapy designation supports our goal of making the first approved reversal agent for ticagrelor available to patients and physicians as soon as possible. We look forward to working closely with the FDA throughout the expedited development process."

**About PB2452**

PB2452 is a novel, recombinant, human monoclonal antibody antigen-binding fragment, or Fab fragment, designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. In Phase 1 clinical and preclinical studies, PB2452 achieved immediate and sustained reversal of ticagrelor's antiplatelet activity, demonstrating the potential to bring life-saving therapeutic benefit by increasing the safety of ticagrelor and mitigating concerns regarding the bleeding risk associated with antiplatelet drugs. There are currently no approved reversal agents for ticagrelor or any other antiplatelet drugs.

**About PhaseBio**

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies to treat orphan diseases, with an initial focus on cardiopulmonary disorders. The company's lead development candidate is PB2452, a novel reversal agent for the antiplatelet therapy ticagrelor. PhaseBio is also leveraging its proprietary elastin-like polypeptide ("ELP") technology platform to develop therapies with the potential for less-frequent dosing and improved pharmacokinetics. PhaseBio's second product candidate PB1046, which is based on ELP, is a once-weekly vasoactive intestinal peptide receptor agonist for the treatment of pulmonary arterial hypertension.

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

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