
**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): March 10, 2021

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 x

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. x

Item 1.01 Entry into a Material Definitive Agreement

On March 10, 2021, PhaseBio Pharmaceuticals, Inc. (the “**Company**”) entered into a Supply Agreement (the “**Agreement**”) with BioVectra Inc. (“**BioVectra**”) for the manufacture and supply by BioVectra of bulk drug substance (API) for the Company’s lead product candidate bentracimab, also known as PB2452 (“**Product**”), for commercial distribution following regulatory approval. Under the terms of the Agreement, BioVectra has committed to maintaining capacity to manufacture an agreed number of batches of Product each year, and the Company has committed to purchase a specified minimum number of batches of Product per year (“**Minimum Annual Commitment**”), although the Company is free to contract with third parties for the manufacture of Product.

The Company will pay a supply price per batch of Product (the “**Supply Price**”) to be determined after the manufacturing process for Product is validated in accordance with the Agreement (“**Validation**”), plus the cost of certain consumables, raw materials, and third-party testing. The parties have agreed that the initial Supply Price of Product will be within a specified percentage of the estimated supply price set forth in the Agreement and will remain firm through the second anniversary of Validation. Thereafter, on an annual basis following the second anniversary of Validation, either party may propose adjustments to the Supply Price for increases or decreases based on a specified inflation rate, subject to a maximum inflation adjustment per year, and BioVectra may propose adjusting the supply price beyond that inflation rate if it can document extraordinary increases or decreases in costs, subject to a specified maximum percentage increase or decrease per year.

Pursuant to the Minimum Annual Commitments, the Company is obligated to purchase a minimum of (i) approximately \$14 million of batches of Product in years 2022 through 2023, (ii) approximately \$37 million of batches of Product in 2024, and (iii) approximately \$48 million of batches of Product in each of years 2025 through 2031. In the event the Company does not purchase the applicable Minimum Annual Commitment in a given year, the Company will be obligated to make a payment to BioVectra in an amount equal to the then-applicable Supply Price per batch multiplied by the difference between the Minimum Annual Commitment for such year and the number of batches of Product the Company actually purchased in such year (“**Minimum Shortfall Payment**”), except in the event that BioVectra was unable to deliver the number of batches ordered by the Company in such year. In the event of certain serious or extended failures by BioVectra to supply Product in the quantities ordered by the Company in a given year, the Company’s Minimum Annual Commitment for such year (and potentially one or more subsequent years) will be subject to reduction, and the Company’s obligation to make a Minimum Shortfall Payment for such year (and potentially one or more subsequent years) will be waived. The Company will have the right to reduce the Minimum Annual Commitments for the year 2026 and subsequent years by up to a specified maximum percentage per year. Further, if the Company is only able to obtain regulatory approval for products incorporating Product in only one of the U.S. or Europe, BioVectra and the Company have agreed to discuss in good faith an amendment to the Agreement to reflect decreased requirements for Product and impacts to the Supply Price to reflect lower volume commitments.

The initial term of the Agreement commences on the effective date of the Agreement and continues until the tenth anniversary of Validation. The term of the Agreement may be extended for additional one-year periods upon mutual agreement of the parties. Either party may terminate the Agreement in the event of an uncured material breach by the other party or upon the occurrence of certain events of insolvency of the other party. The Company may terminate the Agreement (i) in the event of certain regulatory compliance failures by BioVectra or any person employed or retained by it to perform services under the Agreement, or (ii) subject to payment of a termination fee to BioVectra (the amount of which decreases over the term of the Agreement from an initial maximum in the mid-teens of millions of dollars to zero), in the event the Company decides that it will not, or is unable to, pursue regulatory approval or commercialization of products incorporating Product or in the event of termination of the Company’s license to the Product from MedImmune Limited. The Company may also terminate the Agreement without cause and without payment of a termination fee upon 24 months’ notice following the fifth anniversary of regulatory approval of a product incorporating Product by either the U.S. Food and Drug Administration or European Medicines Agency.

The Agreement contains, among other provisions, representation and warranties, indemnification obligations, confidentiality, publicity, audit and inspection, and intellectual property sharing provisions in favor of each party that are customary for an agreement of this nature.

The foregoing summary of the Agreement is not complete and is qualified in its entirety by reference to the text of the Agreement, a copy of which will be filed as an exhibit to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021.

Item 7.01 Regulation FD Disclosure.

On March 11, 2021, the Company issued a press release announcing the Agreement. A copy of this press release is furnished herewith as Exhibit 99.1 to this report. The information contained in the press release furnished as Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), and is not incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated March 11, 2021.

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: March 11, 2021

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



PhaseBio Pharmaceuticals and BioVectra Enter into Supply Agreement to Support Development and Commercialization of Bentracimab

Malvern, PA and San Diego, CA - March 11, 2021 - PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, and BioVectra Inc., an innovative global contract development and manufacturing organization (CDMO), today announced a commercial scale supply agreement for the production of bentracimab, PhaseBio's lead product candidate currently in a global Phase 3 clinical trial. Bentracimab is a novel, human monoclonal antibody fragment that in earlier clinical trials has shown immediate and sustained reversal of the antiplatelet effects of Brilinta® (ticagrelor).

Under the terms of the agreement, BioVectra will provide its integrated CDMO services for the manufacturing of the active pharmaceutical ingredient (API) of bentracimab for use in PhaseBio's ongoing global clinical trials and for global commercial use upon regulatory approval. Utilizing a cost-efficient, E.coli-based manufacturing process at its manufacturing site in Windsor, Nova Scotia, BioVectra recently completed the first GMP run of bentracimab at commercial scale. Going forward, PhaseBio plans to integrate API manufactured at commercial scale at BioVectra into the ongoing Phase 2b and Phase 3 REVERSE-IT clinical trials to support global regulatory filings.

"As we prepare for the next phase of growth for bentracimab, we're pleased to sign this agreement with BioVectra for the commercial supply and development of our novel reversal agent," said Jonathan P. Mow, Chief Executive Officer of PhaseBio Pharmaceuticals. "Having recently expanded our global Phase 3 REVERSE-IT trial into Canada and the European Union, and with other countries on the horizon, the signing of this agreement and the completion of our first commercial-scale manufacturing run are important steps as we continue preparing our regulatory filings and commercialization efforts for bentracimab. We believe BioVectra will be an excellent partner as we move down the path of developing and potentially commercializing the first specific antiplatelet reversal agent for ticagrelor."

Pending approval of the drug by regulators, the partnership will enable PhaseBio to supply bentracimab at launch in the U.S. to key trauma and critical care centers. Based on data from IQVIA®, PhaseBio believes that providing adequate bentracimab supply for initial stocking and demand-based reorders for these key centers will make bentracimab accessible to approximately 80% of the population in the U.S. who are prescribed P2Y₁₂ inhibitors like ticagrelor.

"We're excited to be partnering with PhaseBio under this new commercial agreement for the high-volume scale-up and global supply of bentracimab," said Oliver Technow, Chief Executive Officer of BioVectra. "BioVectra is an expert CDMO with proven, specialized capability in scaling the most complex biologic drug substances produced from fermentation. Leveraging our fully integrated approach and 50 years of experience, our highly-skilled team looks forward to continuing to make a difference in patients' lives by delivering on and supporting PhaseBio's global commercialization of bentracimab from our new, large-scale Microbial Biomanufacturing facility."

About Bentracimab (PB2452)

Bentracimab is a novel, recombinant, human monoclonal antibody antigen-binding fragment designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. In a Phase 1 clinical trial, bentracimab demonstrated the potential to bring life-saving therapeutic benefit through immediate and sustained reversal of ticagrelor's antiplatelet activity, mitigating concerns regarding bleeding risks associated with the use of antiplatelet drugs. The Phase 1 clinical trial of bentracimab in healthy volunteers was published in the *New England Journal of Medicine* in March 2019. In April 2019, bentracimab received Breakthrough Therapy Designation from the FDA. Breakthrough Therapy Designation may be granted by the FDA when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapy. In September 2019, PhaseBio completed a Phase 2a trial in which bentracimab was investigated in older and elderly subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. Additionally, the Phase 2a trial investigated a bentracimab regimen for the reversal of supratherapeutic doses of ticagrelor in healthy younger subjects. In both arms of the trial, bentracimab achieved immediate and sustained reversal of the antiplatelet effects of ticagrelor and was generally well-tolerated, with only minor adverse events reported. These results are consistent with the results observed in healthy younger subjects treated with ticagrelor in the previously published Phase 1 trial. PhaseBio initiated the REVERSE-IT trial, a pivotal Phase 3 clinical trial of bentracimab, in March 2020 to support a Biologics License Application for bentracimab in both major bleeding and urgent surgery indications. 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 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.

About BioVectra

BioVectra is a CDMO that serves global pharmaceutical and biotech companies with full-service cGMP outsourcing solutions for intermediates and active pharmaceutical ingredients (APIs). An innovative and reliable service partner with a strong regulatory history, BioVectra has over 50 years of experience specializing in:

- cGMP microbial fermentation
- Complex chemistry – high potency APIs
- Biologics
- Formulation development

BioVectra operates out of five cGMP facilities in Atlantic Canada. For more information about BioVectra, please visit www.biovectra.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 clinical trials and 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 (“SEC”) filings, including in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 and in our Annual Report on Form 10-K for the year ended December 31, 2020, which we intend to file shortly hereafter. 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.

Contacts

Investors

PhaseBio:

John Sharp
PhaseBio Pharmaceuticals, Inc.
Chief Financial Officer
(610) 981-6506
john.sharp@phasebio.com

BioVectra:

Heather Delage
BioVectra Inc.
Chief Commercial Officer
(902) 566-9116 ext. 6236
hdelage@biovectra.com

Media

PhaseBio:

Will Zasadny
Canale Communications, Inc.
(619) 961-8848
will.zasadny@canalecomm.com

BioVectra:

Jordan MacGregor
BioVectra Inc.
Marketing & Communications Manager
(902) 566-9116 ext. 6376
jmacgregor@biovectra.com