



PhaseBio Reports First Quarter 2020 Financial Results and Recent Business Highlights

May 12, 2020

Initiated PB2452 Phase 3 Trial for the Reversal of the Antiplatelet Effects of Ticagrelor

MALVERN, Pa & SAN DIEGO--(BUSINESS WIRE)--May 12, 2020-- [PhaseBio Pharmaceuticals, Inc.](#) (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today reported financial results from the first quarter ending March 31, 2020 and provided an update on corporate activities.

"The first quarter of 2020 marked an important period of progress for PhaseBio, including the advancement of our lead program PB2452 into a Phase 3 registrational trial," said Jonathan P. Mow, Chief Executive Officer of PhaseBio. "We are continuing to work to open additional clinical sites in the United States and to identify potential clinical sites in both Europe and Asia with our partner SFJ Pharmaceuticals. Although the COVID-19 pandemic is temporarily impacting the pace of site initiation and patient enrollment, we are encouraged that investigators continue to view PB2452 as an important potential option to help treat ticagrelor patients who require emergency surgery or who experience a major bleeding event. During these unprecedented times, we will continue to work to advance our strategic objectives, which are focused on delivering impactful medicines to patients with significant unmet medical needs."

PB2452 Recent Highlights

- **Initiated Phase 3 Clinical Trial for PB2452:** In March 2020, PhaseBio commenced the pivotal Phase 3 trial of PB2452, which will evaluate reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Timing of initiation of new trial sites and patient enrollment is dependent on the sites as they weigh the potential impact of the COVID-19 pandemic on emergency medicine and critical care resources. More information about the Phase 3 trial is available at [ClinicalTrials.gov](#).
- **Granted PRIME Designation for PB2452 from European Medicines Agency:** In February 2020, PhaseBio [announced that PB2452 was granted PRiority MEDicines \(PRIME\) designation](#) by the European Medicines Agency (EMA) for the reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. The EMA prioritizes PRIME designated drugs for special support, including enhanced interactions and dialogue with the EMA during development, as well as a pathway for accelerated evaluation and review for marketing authorization.
- **Received written scientific advice confirming the PB2452 clinical development plan:** In February 2020, PhaseBio [announced the receipt of written guidance](#) from the Committee for Medicinal Products for Human Use (CHMP) of the EMA that generally agrees with PhaseBio's proposed development plan for PB2452. After reviewing the scientific advice from CHMP and based on prior interactions with the U.S. Food and Drug Administration (FDA), PhaseBio believes that the development plan for PB2452 has been designed to support regulatory filings in the United States and the European Union.
- **Entered into financing and co-development collaboration with SFJ Pharmaceuticals®:** In January 2020, PhaseBio [announced a financing and co-development collaboration with SFJ Pharmaceuticals](#) (SFJ) to support the development of PB2452. Under the terms of the agreement, SFJ has agreed to fund up to \$120 million to support the clinical development of PB2452 and to assume a central role in global clinical development and regulatory activities for PB2452 outside of the United States. SFJ agreed to fund \$90 million of development expenses through the end of 2021 and up to an additional \$30 million based on PhaseBio meeting specific, pre-defined clinical milestones for PB2452. To date, SFJ has made an initial payment to PhaseBio of \$10 million, which was received in the first quarter of 2020, and has reimbursed PhaseBio for other clinical trial costs.

Other Pipeline and Operational Highlights:

- **PB1046 Clinical Trial Enrollment Update:** PhaseBio temporarily paused enrollment of new patients in its Phase 2b study of PB1046 as a precaution to minimize potential exposure of this patient population at high risk of serious illness from COVID-19. However, the company also informed investigators that they could continue dosing drug and performing assessments for current trial participants if they deemed it appropriate and such activities were permitted by their respective institutions. The company has recently begun working with trial sites to help design plans to enable them to resume new patient enrollment, once appropriate and permitted, and certain sites have resumed screening patients on a limited basis. Additionally, the company continues to identify new trial sites for future initiation. With patient safety being the top priority, the company will continue to actively monitor the situation, consult with necessary regulatory agencies and provide updates as they become available.
- **Case Study of PB1046 presented at Pulmonary Vascular Research Institute World Congress:** In February 2020, PhaseBio [announced presentation of data from a patient](#) who received more than 18 months of treatment with PB1046, the company's first-in-class,

sustained-release vasoactive intestinal peptide (VIP) analogue being evaluated for the treatment of patients with pulmonary arterial hypertension (PAH). The data demonstrated clinically meaningful improvements in all of the hemodynamic parameters assessed, which were sustained for up to three months after the last dose was administered. All three patients in the Phase 1b/2a pilot study completed the eight-week study with no drug-related serious adverse events, and PB1046 appeared to be well tolerated with only mild injection site erythema.

- Acquired novel oral aldosterone synthase inhibitor for development in treatment-resistant hypertension:** In January 2020, PhaseBio [announced it had signed an agreement](#) with Viamet Pharmaceuticals Holdings, LLC and its wholly-owned subsidiary, Selenity Pharmaceuticals (Bermuda), Ltd., under which PhaseBio acquired all of the assets and intellectual property rights related to certain novel aldosterone synthase inhibitors, including the company's lead development compound, now called PB6440, being developed for treatment-resistant hypertension. In preclinical studies completed to date, PB6440 was observed to be a highly potent and selective inhibitor of aldosterone synthase (CYP11B2) versus the closely-related steroid 11 β -hydroxylase enzyme (CYP11B1). PB6440 demonstrated dose-dependent aldosterone reduction without a significant increase in 11-deoxycorticosterone or deoxycortisol in both rodent and primate models.

First Quarter 2020 Financial Results

Cash Position

Cash and cash equivalents at March 31, 2020 were \$59.4 million, compared to \$74.0 million at December 31, 2019. The decrease reflects cash used in operating activities, partially offset by receipt of the initial \$10.0 million payment from SFJ as part of the PB2452 financing and co-development agreement.

Results of Operations

Three Months Ended March 31, 2020

PhaseBio reported a net loss of \$14.9 million for the three months ended March 31, 2020, which compared with a net loss of \$7.3 million for the same period in 2019. This resulted in a net loss of \$0.52 per share for the three months ended March 31, 2020, compared to a net loss of \$0.30 per share for the corresponding period in 2019, on both a basic and diluted basis.

Grant revenues were \$0.3 million for the three months ended March 31, 2020, as PhaseBio incurred allowable costs qualifying for reimbursement under the government grants. Grant revenues for the same period in 2019 were \$0.7 million.

Research and development expense increased to \$11.4 million for the three months ended March 31, 2020, compared to \$5.7 million for the three months ended March 31, 2019, reflecting an increase in manufacturing and clinical activities related to PB2452 and PB1046 as well as other preclinical development activities.

General and administrative expense increased to \$3.2 million for the three months ended March 31, 2020, compared to \$2.3 million for the three months ended March 31, 2019, primarily attributable to increases in professional services, personnel, insurance and business travel-related expenses.

About PhaseBio

[PhaseBio Pharmaceuticals, Inc.](#) is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases. The company's pipeline includes: PB2452, a novel reversal agent for the antiplatelet therapy ticagrelor; 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 PB1046, 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 success of our collaboration with SFJ, including whether we will receive all of the contemplated funding under the co-development agreement, 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 March 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.

PhaseBio Pharmaceuticals, Inc.
Condensed Statements of Operations
 (in thousands, except share and per share amounts)
 (unaudited)

	Quarter Ended March 31,	
	2020	2019
Grant revenue	\$ 320	\$ 653
Operating expenses:		
Research and development	11,449	5,721
General and administrative	3,159	2,316

Total operating expenses	14,608	8,037
Loss from operations	(14,288)	(7,384)
Other (expense) income	(617)	91
Net loss	<u>\$ (14,905)</u>	<u>\$ (7,293)</u>
Net loss per common share, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (0.30)</u>
Weighted average common shares outstanding, basic and diluted	<u>28,773,274</u>	<u>24,498,388</u>

PhaseBio Pharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands)
(unaudited)

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
Assets:		
Cash and cash equivalents	\$ 59,441	\$ 74,025
Other receivables, prepaid expenses and other current assets	13,100	4,798
Property and equipment, net	2,637	1,924
Operating lease right-of-use assets	1,648	1,715
Other non-current assets	32	32
Total assets	<u>\$ 76,858</u>	<u>\$ 82,494</u>
Liabilities and stockholders' equity:		
Current portion of long-term debt	\$ 3,686	\$ 2,378
Accounts payable, accrued expenses and other current liabilities	3,809	6,101
Long-term debt, net	11,058	12,326
Operating lease liabilities, net	1,438	1,508
Development derivative liability	3,086	—
Other long-term liabilities	295	203
Stockholders' equity	<u>53,486</u>	<u>59,978</u>
Total liabilities and stockholders' equity	<u>\$ 76,858</u>	<u>\$ 82,494</u>

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