



PhaseBio Reports Second-Quarter 2021 Financial Results and Recent Business Highlights

August 12, 2021

Entered exclusive licensing agreement with Alfasigma S.p.A with up to \$245 million in milestone payments and tiered royalty payments for development and commercialization of bentracimab in European and other key markets

Achieved interim enrollment milestone with first 143 bentracimab patients enrolled in the REVERSE-IT pivotal Phase 3 trial, with top-line results from interim analysis expected later this year

Bentracimab Phase 2b trial enrollment completed; safety and efficacy data will supplement Phase 3 interim results, with combined data package planned to serve as the basis for a Biologics License Application (BLA) submission in mid-2022

Cash and Equivalents of \$64.5 million as of June 30, 2021

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Aug. 12, 2021-- [PhaseBio Pharmaceuticals, Inc.](#) (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today provided an update on corporate activities and reported second-quarter 2021 financial results.

"Since the end of the first quarter, the PhaseBio team has made excellent progress with our lead program, bentracimab, including completing enrollment of the first 143 patients in our pivotal Phase 3 REVERSE-IT trial, completing enrollment in the Phase 2b bentracimab trial and signing an exclusive licensing agreement with Alfasigma S.p.A for commercialization in nearly 50 countries across Europe and the Commonwealth of Independent States," said Jonathan P. Mow, Chief Executive Officer, PhaseBio Pharmaceuticals. "We believe these clinical and strategic milestones position PhaseBio to finish 2021 with significant momentum. The bentracimab program remains on track, and with Alfasigma taking the commercial lead across Europe and other key markets, we believe PhaseBio is well positioned to focus on the BLA submission for bentracimab and prepare for expected commercial launch in the United States."

Program Highlights and Corporate Updates

- **Achieved Enrollment Milestones Supporting Interim Analysis of REVERSE-IT Global Phase 3 Trial of Bentracimab for Reversal of Antiplatelet Effects of Ticagrelor:** In August 2021, PhaseBio announced that it had completed enrollment of the first 143 patients in its pivotal Phase 3 REVERSE-IT trial for its lead product candidate bentracimab, 138 of whom required urgent surgery or an invasive procedure and five of whom experienced uncontrolled major or life-threatening bleeding. In total, the REVERSE-IT trial is expected to enroll approximately 200 major bleeding or urgent surgery patients at sites in the United States, Canada, European Union and China. Based on prior guidance following the End of Phase 1 Meeting with the U.S. Food and Drug Administration (FDA) to balance the two patient populations, the REVERSE-IT trial does not allow enrollment of more than approximately two thirds of either the uncontrolled major or life-threatening bleeding population or urgent surgery or invasive procedure population. Because the total number of patients enrolled to date includes 138 patients who required urgent surgery or an invasive procedure, the surgery cohort of the trial has been fully enrolled. With the successful completion of enrollment in this surgery cohort, REVERSE-IT trial sites have shifted focus to enrolling patients with uncontrolled major or life-threatening bleeding events. The Company is continuing to attempt to accelerate enrollment of patients with uncontrolled major or life-threatening bleeding, including by working to increase the number of enrolling clinical trial sites in the United States, Canada and the European Union, as it believes that a broader site footprint will increase the probability of enrolling these patients. The FDA also previously indicated that an interim analysis of the first approximately 100 patients enrolled in the REVERSE-IT trial would be sufficient to support the submission of a BLA for accelerated approval. The FDA recommended that the 100 patients comprising the interim analysis include approximately 50 patients from each of the uncontrolled major or life-threatening bleeding population and the urgent surgery or invasive procedure population, although the FDA noted that whether there are an adequate number of patients from either cohort would be a review issue and considered in the context of other data submitted with the BLA. The Company is commencing preparation of the BLA and targeting a BLA submission to the FDA in mid-2022.
- **Completed Enrollment in Bentracimab Phase 2b trial:** In August 2021, PhaseBio announced the completion of enrollment in the randomized, double-blind, placebo-controlled Phase 2b trial of bentracimab. The Phase 2b trial enrolled 200 healthy older and elderly (ages 50 to 80) subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin; 150 subjects were randomized to receive bentracimab, with reversal of the antiplatelet effects of ticagrelor, as measured by the VerifyNow® PRUtest biomarker, serving as the primary endpoint for the trial. Top-line results from the Phase 2b trial are expected later this year. The Phase 2b trial was designed to supplement the safety and efficacy results that will be included in the BLA submission.
- **Announced Approval of Bentracimab IND in China:** In August 2021, PhaseBio [announced](#) that the Investigational New Drug (IND) application for bentracimab submitted to the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) in collaboration with development partner, SFJ Pharmaceuticals (SFJ), has been approved. PhaseBio and SFJ anticipate enrolling the first patients at sites in China later in 2021. Patients enrolled in China are expected to contribute to the completion of full enrollment of

the trial, post interim analysis. In January 2020, PhaseBio announced a financing and co-development partnership with SFJ Pharmaceuticals, and since this time, SFJ has been leading clinical development efforts in China. PhaseBio retains commercial rights to bentracimab in China and is pursuing prospective commercial partners to license the marketing rights in China and other countries in the Asia-Pacific region.

- **Entered European Licensing Agreement with Alfasigma for Commercialization of Bentracimab:** In June 2021, PhaseBio [announced](#) an exclusive licensing agreement with Alfasigma, a privately owned specialty pharmaceutical company focused on commercializing medicines in Europe and other key markets, for the commercialization of bentracimab. Under the terms of the license agreement, PhaseBio received a \$20 million upfront payment and will be eligible to receive up to \$35 million in pre-revenue regulatory milestones and up to \$190 million in payments contingent upon the achievement of certain sales milestones. PhaseBio will also receive tiered royalties on net sales, with percentages starting in the low double digits and escalating up to the mid-twenties.
- **Presented Real-World Healthcare Cost and Bleeding Cost Data Featured at the International Society for Pharmacoeconomic and Outcomes Research (ISPOR) Virtual 2021 Conference:** In May 2021, PhaseBio [presented](#) a poster analysis of the IBM® MarketScan® Commercial and Medicare Supplemental claims databases and focused on patients newly initiating a P2Y₁₂ inhibitor, factor Xa inhibitor or dabigatran between 2014 and 2018. Among other things, results of the analyses demonstrated that, in the year prior to initiating therapy, total healthcare costs were higher among P2Y₁₂ inhibitor patients compared to factor Xa and dabigatran patients. These conference proceedings present compelling evidence of an unmet medical and pharmacoeconomic need for an effective reversal agent for patients treated with P2Y₁₂ inhibitors.
- **Presented Real-World Bleeding and Surgery Data Featured at The American College of Cardiology's 70th Annual Scientific Session:** In May 2021, PhaseBio [presented](#) a poster summarizing an analysis of the IBM® MarketScan® Commercial and Medicare Supplemental claims databases and focused on patients newly initiating a P2Y₁₂ inhibitor, factor Xa inhibitor or dabigatran between 2014 and 2018. The results of the analysis demonstrated that patients receiving P2Y₁₂ inhibitors presented a significantly higher burden of baseline comorbid conditions than factor Xa and dabigatran patients. Additionally, the results indicate that bleeding complications and medical procedures are common in patients taking antithrombotic medications. PhaseBio and the authors believe this study demonstrates an unmet need for an effective reversal agent for patients prescribed P2Y₁₂ inhibitors.
- **SFJ Financing and Co-Development Agreement Update:** From execution of the co-development agreement through June 30, 2021, SFJ has funded or reimbursed \$77.5 million of clinical trial costs and other expenses of the initial \$90.0 million commitment under the agreement, leaving \$12.5 million of funding remaining available to support the bentracimab Phase 3 program. PhaseBio is eligible to receive up to an additional \$30 million of funding if specific, pre-defined clinical development milestones for bentracimab are met.

Second-Quarter 2021 Financial Results

- Cash and cash equivalents at June 30, 2021 were \$64.5 million, compared to \$28.1 million at December 31, 2020. The increase reflects proceeds from the March 2021 offering of common stock, partially offset by cash used in operating activities.
- Sublicense revenue for the quarter was \$10.3 million and reflects recognition of a portion of the upfront milestone payment received as part of the Alfasigma licensing agreement.
- Net loss for the quarters ended June 30, 2021 and 2020 was \$28.7 million.
- Research and development expense increased to \$27.4 million for the quarter ended June 30, 2021, as compared to \$20.9 million for the same period in 2020, driven by an increase in manufacturing, clinical and nonclinical development activities related to bentracimab.
- General and administrative expense increased to \$4.0 million for the quarter ended June 30, 2021, compared to \$3.2 million for the same period in 2020.

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; pemziviptadil (PB1046), a once-weekly vasoactive intestinal peptide (VIP) 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 pemziviptadil, 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, and follow us on Twitter [@PhaseBio](#) and [LinkedIn](#).

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," "potential," "projects," "target," "will," "would" 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 timing of availability or disclosure of data from those clinical trials and the timing of planned regulatory submissions, 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, including through our partnerships with Alfasigma and SFJ. 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, 2021. 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 Balance Sheets
(in thousands)
(unaudited)

	June 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	\$ 64,456	\$ 28,122
Receivable from sublicense	18,400	—
Prepaid expenses and other current assets	5,644	12,027
Property and equipment, net	10,379	8,224
Operating lease right-of-use assets	1,701	1,927
Other non-current assets	57	57
Total assets	<u>\$100,637</u>	<u>\$ 50,357</u>
Liabilities and stockholders' deficit:		
Current portion of long-term debt	\$ 5,384	\$ 5,355
Current portion of deferred sublicense revenue	1,424	—
Accounts payable, accrued expenses and other current liabilities	9,366	9,605
Long-term debt, net	4,073	6,773
Operating lease liabilities, net	1,306	1,548
Deferred sublicense revenue, net	8,238	—
Development derivative liability	89,329	51,719
Other long-term liabilities	692	559
Stockholders' deficit	<u>(19,175)</u>	<u>(25,202)</u>
Total liabilities and stockholders' deficit	<u>\$100,637</u>	<u>\$ 50,357</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Sublicense revenue	\$ 10,337	\$ —	\$ 10,337	\$ —
Grant revenue	—	—	—	320
Total revenue	<u>10,337</u>	<u>—</u>	<u>10,337</u>	<u>320</u>
Operating expenses:				
Research and development	27,366	20,856	49,686	32,305
General and administrative	4,024	3,242	7,351	6,401
Total operating expenses	<u>31,390</u>	<u>24,098</u>	<u>57,037</u>	<u>38,706</u>
Loss from operations	<u>(21,053)</u>	<u>(24,098)</u>	<u>(46,700)</u>	<u>(38,386)</u>
Other (expense) income	(6,026)	(4,044)	(7,737)	(4,661)
Net loss before income taxes	<u>(27,079)</u>	<u>(28,142)</u>	<u>(54,437)</u>	<u>(43,047)</u>
Provision for income taxes	1,600	—	1,600	—
Net loss	<u>\$ (28,679)</u>	<u>\$ (28,142)</u>	<u>\$ (56,037)</u>	<u>\$ (43,047)</u>
Net loss per common share, basic and diluted	<u>\$ (0.60)</u>	<u>\$ (0.98)</u>	<u>\$ (1.41)</u>	<u>\$ (1.50)</u>
Weighted average common shares outstanding, basic and diluted	<u>47,985,871</u>	<u>28,805,238</u>	<u>39,680,408</u>	<u>28,789,256</u>

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