PhaseBio Pharmaceuticals Reports Fourth Quarter and Full-Year 2021 Financial Results and Provides Recent Business Highlights

March 24, 2022

Achieved key clinical milestones for bentracimab program, with positive results from both the completed Phase 2b trial and interim analysis of the ongoing REVERSE-IT global Phase 3 trial

Company remains on track to submit Biologics License Application (BLA) for bentracimab in mid-2022 and is preparing for expected commercialization in U.S.

PB6440, the company's aldosterone synthase inhibitor in development for resistant hypertension, on track for submission of an Investigational New Drug application (IND) in the second half of 2022

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Mar. 24, 2022-- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiovascular diseases, today reported financial results for the fourth quarter and full-year ended December 31, 2021, and provided an update on corporate activities.

"Our team continues to make notable progress in advancing our lead product candidate bentracimab," said Jonathan Mow, Chief Executive Officer of PhaseBio Pharmaceuticals. "Our progress throughout 2021 was highlighted by positive interim Phase 3 results from our bentracimab clinical program, our entry into a commercial scale supply agreement with BioVectra and a European licensing agreement with Alfasigma S.p.A, and the achievement of multiple clinical and regulatory milestones. I commend the dedication of our team, which has kept us on track for a planned Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) in mid-2022. Looking ahead, we remain focused on executing on our strategic business and clinical objectives, including preparing for the expected commercial launch of bentracimab in the U.S. and submitting an IND for PB6440, our aldosterone synthase inhibitor in development for resistant hypertension and potentially other cardio-renal indications."

Bentracimab Program Highlights

- **Announced Completion of Bentracimab BLA Enabling Manufacturing:** In March 2022, PhaseBio announced the completion of the drug substance and drug product Process Performance Qualification (PPQ) campaign for bentracimab. The PPQ campaign consisted of multiple commercial scale runs required for the validation of the bentracimab manufacturing process and the demonstration of batch-to-batch manufacturing consistency, at commercial scale. The inclusion of commercial-scale material in the company's completed Phase 2b trial and ongoing Phase 3 trial for bentracimab, coupled with the completion of the PPQ campaign, positions PhaseBio to be ready to supply global demand for bentracimab at launch, once approved. PhaseBio remains on track to submit the bentracimab BLA to the FDA in mid-2022.

- **Published Positive Interim Results from the Pivotal REVERSE-IT Phase 3 Trial of Bentracimab in NEJM Evidence:** In December 2021, PhaseBio published interim results from REVERSE-IT (Rapid and SustainEd ReVERSal of TicagrElor – Intervention Trial) in the New England Journal of Medicine Evidence, a new digital journal from the NEJM (New England Journal of Medicine) Group. REVERSE-IT is PhaseBio's ongoing pivotal Phase 3 trial of its lead product bentracimab, which is designed to study the reversal of the antiplatelet effects of ticagrelor in patients who present with a need for urgent surgery or an invasive procedure or who are experiencing uncontrolled major or life-threatening bleeding. The results, previously presented in a Late-Breaking Science Session at the American Heart Association's 2021 Scientific Sessions, indicated that the Phase 3 trial of bentracimab achieved both the primary reversal endpoint and the co-primary endpoint of clinical hemostasis, and had no drug-related serious adverse events.

- **Announced Positive Interim Results from Pivotal REVERSE-IT Phase 3 Trial of Bentracimab and Presented at the American Heart Association's 2021 Scientific Sessions:** In November 2021, PhaseBio announced positive interim results from REVERSE-IT. The prespecified interim analysis of 150 enrolled patients demonstrated that bentracimab achieved the primary endpoint of the trial by immediately and sustainably reversing the antiplatelet effects of ticagrelor, as measured by the point-of-care VerifyNow® PRUTest® platelet function assay (VerifyNow). More than 90% of eligible patients achieved the co-primary endpoint of the trial, defined as good or excellent hemostasis within 24 hours of initiation of bentracimab therapy. Non-fatal thrombotic events were reported in 5.3% of patients, with none considered by investigators to be related to bentracimab. Bentracimab appeared generally well tolerated with no drug-related serious adverse events. The most common adverse events were related to pain associated with surgical procedures and not considered related to bentracimab. The results were presented by Deepak L. Bhatt, M.D., M.P.H., Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital and professor at Harvard Medical School, during a Late-Breaking Science Session at the 2021 American Heart Association Scientific Sessions.

- **Announced Topline Results from Bentracimab Phase 2b Trial:** In November 2021, PhaseBio announced topline data from its Phase 2b clinical trial of bentracimab, which was conducted in healthy, older volunteers 50-80 years old. The Phase 2b trial achieved its primary

efficacy endpoint, which was the reversal of the antiplatelet effects of ticagrelor in actively treated subjects versus placebo, as measured using the point-of-care VerifyNow assay. Treatment with bentracimab in the Phase 2b trial had a safety profile consistent with the Phase 1 and 2a trials previously completed by the company, with no drug-related serious adverse events or thrombotic events reported in the trial. The Phase 2b results have been accepted for presentation in a Late Breaking Clinical Research session at the American College of Cardiology Annual Scientific Session & Expo being held in Washington, D.C., from April 2-4, 2022.

- **Announced Approval of Bentracimab IND Application in China:** In August 2021, PhaseBio announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) had approved the Investigational New Drug (IND) application for bentracimab submitted by the company, in collaboration with its development partner, SFJ Pharmaceuticals (SFJ). The IND authorizes PhaseBio and SFJ to begin enrolling patients in China into the REVERSE-IT trial. PhaseBio and SFJ expect to enroll the first patients at sites in China in the first half of 2022. Additionally, bentracimab was granted Breakthrough Therapy Designation from CDE in December 2021. Breakthrough Therapy Designation from the NMPA 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. Patients enrolled in China will contribute to the completion of full enrollment of the REVERSE-IT trial, post interim analysis. In January 2020, PhaseBio announced a financing and co-development partnership with SFJ, pursuant to which 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 S.p.A. for Commercialization of Bentracimab:** In June 2021, PhaseBio entered an exclusive licensing agreement with Alfasigma S.p.A., 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 be entitled to receive tiered royalties on net sales, with percentages starting in the low double digits and escalating up to the mid-twenties. The collaboration reinforces the global bentracimab opportunity, and positions bentracimab, if approved, to be accessible to the largest pool of ticagrelor patients in the world.

- **Announced Supply Agreement with BioVectra to Support Development and Commercialization of Bentracimab:** In March 2021, PhaseBio announced a commercial scale supply agreement with BioVectra, an innovative global contract development and manufacturing organization (CDMO), for the production of bentracimab. 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 Phase 2b and Phase 3 clinical trials and for global commercial supply if bentracimab receives regulatory approval.

- **Expanded REVERSE-IT Trial for Bentracimab into the European Union and Dosed First Patients:** In January 2021, PhaseBio announced that, working with its financing and co-development partner SFJ Pharmaceuticals, the company had expanded the REVERSE-IT trial into the European Union, having opened trial sites for enrollment and begun dosing its first patients.

Other Pipeline Updates

- **Provided Pemziviptadil (PB1046) Program Update:** In December 2021, PhaseBio announced that the company voluntarily ended its Phase 2b trial of pemziviptadil (PB1046) in pulmonary arterial hypertension (PAH) due to COVID-19 impacts on manufacturing, associated drug supply and the rate of enrollment in the study. The Phase 2b trial of pemziviptadil, named the VIP trial (Vasoactive Intestinal Peptide in adult patients with PAH), successfully enrolled more than 50% of the study's target population before ending. After a strategic review, the company has decided to stop further development of pemziviptadil in order to reprioritize resources and capital towards pre-commercialization activities for bentracimab and the advancement of other pipeline programs, including PB6440.

Operational Updates

- **Expanded Executive Management Team:** In November 2021, PhaseBio announced the appointment of Jonathan J. Birchall as Chief Commercial Officer. Mr. Birchall leads PhaseBio's efforts to build a critical care focused commercial organization to support the U.S. launch of bentracimab, once approved.

- **Appointed New Member to Board of Directors:** In September 2021, PhaseBio announced the appointment of William D. Humphries to the company's board of directors.

- **Completed Underwritten Public Offering of Common Stock:** In March 2021, PhaseBio closed an underwritten public offering of 18.4 million shares of its common stock at a price to the public of $3.50 per share, including the full exercise of the underwriters' option to purchase an additional 2.4 million shares. The net proceeds to PhaseBio from the offering, after deducting the underwriting discounts and commissions and other estimated offering expenses, were approximately $60.2 million.

- **SFJ Financing and Co-Development Agreement Update:** In January 2020, PhaseBio entered into the SFJ Agreement, pursuant to which SFJ provides the company funding to support the global development of bentracimab. Under the agreement, SFJ agreed to pay the company up to $120.0 million to support the clinical development of bentracimab. In addition to $90.0 million of initial funding, the company has elected to receive an additional $30.0 million of funding having met specific, pre-defined clinical development milestones for bentracimab. From the inception of the SFJ Agreement through December 31, 2021, SFJ has provided funding and paid for amounts on the company's behalf in the aggregate amount of $91.3 million. PhaseBio expects that SFJ will fund or reimburse an additional $28.7 million of clinical trial costs and other expenses.

Fourth-Quarter and Full-Year 2021 Financial Results

Cash Position

- Cash and cash equivalents at December 31, 2021, were $41.8 million, compared to $28.1 million at December 31, 2020. The increase reflects the net proceeds from the company's March 2021 offering of common stock, offset by cash used in operating activities.

Quarter Ending Dec. 31, 2021

- Net loss for the quarter was $43.1 million, compared to a net loss of $30.4 million for the prior-year period.
- Research and development expense increased to $27.4 million, as compared to $22.4 million for the same period in 2020. The increase was primarily attributable to increases in clinical and drug production activities related to bentracimab, depreciation costs for equipment related to the manufacturing of bentracimab, personnel costs and costs associated with our general research efforts.
- General and administrative expense increased to $4.9 million, compared to $3.6 million for prior-year period.

Year Ending Dec. 31, 2021

- Net loss for the year was $131.1 million, compared to a net loss of $98.6 million for the prior-year period.
- Research and development expense increased to $102.1 million, as compared to $72.1 million for the same period in 2020, driven by an increase in manufacturing, clinical and nonclinical development activities related to bentracimab, pemziviptadil and PB6440.
- General and administrative expense increased to $16.1 million, compared to $13.1 million for prior-year period, primarily due to increases in professional services, personnel, and insurance-related expenses.

About Bentracimab (PB2452)

Bentracimab is a novel, recombinant, human monoclonal antibody antigen-binding fragment designed to reverse the antiplatelet activity of ticagrelor in patients who present with uncontrolled bleeding or require surgery. 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 this antiplatelet drug. Data from 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. In September 2019, PhaseBio completed a Phase 2a trial in which bentracimab was investigated in healthy, older 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 November 2021, PhaseBio completed a Phase 2b trial in which bentracimab was investigated in healthy, older subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. In all active treatment arms in both the Phase 2a and Phase 2b trials, 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 REVERSE-IT, a pivotal Phase 3 clinical trial of bentracimab, in March 2020 to support a potential Biologics License Application for bentracimab to treat patients with uncontrolled bleeding or requiring surgery. Interim results from the Phase 3 REVERSE-IT trial were presented in November 2021 and subsequently published in NEJM Evidence in December 2021.

About PhaseBio

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiovascular diseases. The Company's pipeline includes: bentracimab (PB2452), a novel reversal agent for the antiplatelet therapy ticagrelor; 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, 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, our expectations of additional funding from SFJ, the potential for these product candidates to receive regulatory approval from the FDA, CDE or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed, marketed and commercialized, including having sufficient product supply at launch. 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 Annual Report on Form 10-K for the year ended December 31, 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.
Balance Sheets
(in thousands)

	December 31, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 41,800	$ 28,122
Other receivables, prepaid expenses and other current assets	6,984	12,027
Property and equipment, net	10,230	8,224
Operating lease right-of-use assets	1,469	1,927
Other non-current assets	57	57

Total assets	$ 60,540	$ 50,357
Liabilities and stockholders' (deficit) equity:		
Current portion of long-term debt	$ 5,413	$ 5,355
Current portion of deferred sublicense revenue	1,547	—
Accounts payable, accrued expenses and other current liabilities	20,923	9,605
Long-term debt, net	1,359	6,773
Operating lease liabilities, net	1,073	1,548
Deferred sublicense revenue, net	7,622	—
Development derivative liability	114,843	51,719
Other long-term liabilities	794	559
Stockholders' (deficit) equity	(93,034)	(25,202)
Total liabilities and stockholders' (deficit) equity	$ 60,540	$ 50,357

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

	Quarter Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Sublicense revenue	$ 158	$ —	$ 10,831	$ —
Grant Revenue	—	—	—	320
Total revenue	158	—	10,831	320
Operating expenses:				
Research and development	27,355	22,367	102,107	72,088
General and administrative	4,889	3,611	16,086	13,088
Total operating expenses	32,244	25,978	118,193	85,176
Loss from operations	(32,086)	(25,978)	(107,362)	(84,856)
Other (expense) income	(11,024)	(4,397)	(22,109)	(13,709)
Net loss before income taxes	(43,110)	(30,375)	(129,471)	(98,565)
Provision for income taxes	—	—	1,600	—
Net loss	$ (43,110)	$ (30,375)	$ (131,071)	$ (98,565)
Net loss per common share, basic and diluted	$ (0.90)	$ (1.03)	$ (2.98)	$ (3.39)
Weighted average common shares outstanding, basic and diluted	48,130,645	29,397,718	43,918,996	29,056,304

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