



PhaseBio Pharmaceuticals Reports Second Quarter 2022 Financial Results and Recent Business Highlights

August 12, 2022

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Aug. 12, 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 second quarter ended June 30, 2022, and provided an update on corporate activities.

"The second quarter of 2022 marked a period of continued progress for PhaseBio," said Jonathan Mow, Chief Executive Officer of PhaseBio Pharmaceuticals. "Following a successful meeting with the U.S. Food and Drug Administration (FDA) during our pre-biologics license application (pre-BLA) meeting earlier this year and as previously disclosed, we have been focused on clinical development and regulatory efforts to support a planned BLA submission for our lead program, bentracimab, in the fourth quarter of this year. Additionally, we continue to make progress towards completing initial new drug application (IND) enabling studies for PB6440, our aldosterone synthase inhibitor in development for resistant hypertension. We expect to file our IND for PB6440 in the first half of 2023 and to initiate first-in-human trials in mid-2023."

Program Highlights

- **SFJ Financing and Co-Development Agreement Update:** In January 2020, PhaseBio entered into an agreement with SFJ Pharmaceuticals (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 June 30, 2022, SFJ has provided funding and paid for amounts on the company's behalf in the aggregate amount of \$99.0 million. PhaseBio expects that SFJ will fund or reimburse an additional \$21.0 million of clinical trial costs and other expenses.
- **PB6440 IND enabling studies continue to advance:** In the second quarter of 2022, PhaseBio completed the development and optimization of a robust manufacturing process to support anticipated upcoming proof-of-concept trials, positioning the program for initial GMP manufacturing runs in the fourth quarter of 2022. PB6440 is a highly selective aldosterone synthase inhibitor in development to target treatment resistant hypertension and other indications where elevated aldosterone is known to contribute to disease process, such as uncontrolled hypertension, chronic kidney disease, and heart failure. The drug appears to modulate the renin-angiotensin-aldosterone system, which exhibits a critical role in regulation of systemic blood pressure. According to the American Heart Association, 20% of hypertensive Americans, which potentially represents more than 10 million patients, have not achieved normotensive status despite taking three or more blood pressure drugs; we believe this represents a significant unmet need with a large market potential. PB6440 is undergoing IND-enabling studies, with first human trials targeted for mid-2023.

Quarter Ending June 30, 2022

- Cash and cash equivalents on June 30, 2022, were \$7.8 million, compared to \$41.8 million at December 31, 2021. The decrease primarily reflects cash used in operating activities.
- Net loss for the quarter was \$16.7 million, compared to a net loss of \$28.7 million for the prior-year period.
- Research and development expense for the quarter decreased to \$20.9 million, as compared to \$27.4 million for the same period in 2021. The decrease was primarily attributable to drug manufacturing activity in 2021, study site startup costs for the Phase 2b trial related to bentracimab in 2021, and the voluntary ending of the Phase 2b trial of pemziviaptadil in the fourth quarter of 2021, partially offset by an increase in costs related to development of PB6440, and personnel costs and other costs associated with our general research and development efforts.
- General and administrative expense for the quarter increased to \$4.6 million, compared to \$4.0 million for the prior-year period. The increase was primarily attributable to increases in consulting costs and personnel expenses due to additional headcount.

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 older subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin, with complete results announced and presented in April 2022. 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, including enrollment, 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, EMA 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, and our ability to complete post-approval requirements. 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 March 31, 2022. 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)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Assets:		
Cash and cash equivalents	\$ 7,804	\$ 41,800
Prepaid expenses and other assets	3,760	6,984
Property and equipment, net	9,322	10,230
Operating lease right-of-use assets	1,222	1,469
Other assets	58	57
Total assets	<u>\$ 22,166</u>	<u>\$ 60,540</u>
Liabilities and stockholders' deficit:		
Current portion of long-term debt	\$ 4,073	\$ 5,413
Current portion of deferred sublicense revenue	1,400	1,547
Accounts payable, accrued expenses and other current liabilities	19,206	20,923
Long-term debt, net	—	1,359
Operating lease liabilities, net	869	1,073
Long term portion of deferred sublicense revenue, net	7,443	7,622
Development derivative liability	106,573	114,843
Other long-term liabilities	—	794
Total stockholders' deficit	<u>(117,398)</u>	<u>(93,034)</u>
Total liabilities and stockholders' deficit	<u>\$ 22,166</u>	<u>\$ 60,540</u>

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

	<u>Three Months Ended June 30, 2022</u>		<u>Six Months Ended June 30, 2021</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenue:				
Sublicense revenue	\$ 208	\$ 10,338	\$ 325	\$ 10,338
Total revenue	<u>208</u>	<u>10,338</u>	<u>325</u>	<u>10,338</u>
Operating expenses:				
Research and development	20,939	27,366	35,275	49,686
General and administrative	4,581	4,025	8,590	7,352

Total operating expenses	25,520	31,391	43,865	57,038
Loss from operations	(25,312)	(21,053)	(43,540)	(46,700)
Other income (expense)	8,647	(6,026)	15,734	(7,737)
Net loss before income taxes	(16,665)	(27,079)	(27,806)	(54,437)
Provision for income taxes	—	1,600	—	1,600
Net loss	<u>\$ (16,665)</u>	<u>\$ (28,679)</u>	<u>\$ (27,806)</u>	<u>\$ (56,037)</u>
Net loss per common share, basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.60)</u>	<u>\$ (0.57)</u>	<u>\$ (1.41)</u>
Weighted average common shares outstanding, basic and diluted	<u>49,182,813</u>	<u>47,985,871</u>	<u>48,910,437</u>	<u>39,680,408</u>

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