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

May 16, 2022

Held successful Type B pre-biologics license application (BLA) meeting with U.S. FDA for future submission of BLA for bentracimab

BLA submission for bentracimab is planned for early in the fourth quarter of 2022 and PhaseBio is preparing for commercialization in U.S., if approved

Presented positive results from Phase 2b trial for bentracimab at ACC.22

Completed the Process Performance Qualification (PPQ) campaign demonstrating commercial scale manufacturing ability for bentracimab

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--May 16, 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 first quarter ended March 31, 2022, and provided an update on corporate activities.

"The first quarter of 2022 was a period of significant momentum for PhaseBio, as we continued to advance our pipeline and lay the groundwork for the commercialization of bentracimab in the United States. Our progress was driven primarily by the successful completion of a Type B pre-BLA meeting with the FDA, which positions us to submit our BLA early in the fourth quarter of this year," said Jonathan Mow, Chief Executive Officer of PhaseBio Pharmaceuticals. "In addition to receiving encouraging formal written feedback from federal regulators, we were pleased to announce positive results from our completed Phase 2b trial for bentracimab at ACC.22, data that will be key in bolstering our BLA submission package. We remain focused on advancing our broader pipeline for cardiovascular conditions, swiftly moving our planned BLA submission forward, and progressing our pre-commercial and manufacturing capabilities as we work to deliver the first ticagrelor reversal agent to patients with a significant unmet medical need, if approved."

Bentracimab Program Highlights

- **Announced Successful Pre-BLA Meeting with U.S. FDA for Bentracimab:** In May 2022, PhaseBio announced the completion of a successful Type B pre-biologics license application (pre-BLA) meeting with the U.S. Food and Drug Administration (FDA) for bentracimab. Based on this pre-BLA meeting and the formal written minutes received from the FDA, PhaseBio intends to submit the BLA for bentracimab early in the fourth quarter of 2022. During the pre-BLA meeting, the FDA agreed that the company's plans to submit a BLA with data from 25-30 patients with uncontrolled bleeding, together with data from the fully completed surgical cohort, appeared reasonable to support a label with both bleeding and surgical indications, but would be a review issue based on the data submitted. To date, and subject to final adjudication, the REVERSE-IT trial has enrolled 35 patients taking ticagrelor who experienced uncontrolled bleeding events. PhaseBio previously intended to base its BLA submission on data from the interim analysis of the Phase 3 REVERSE-IT trial published in December 2021, and the recently presented Phase 2b trial data. Based on the feedback received from the FDA during the pre-BLA meeting, PhaseBio will include in the BLA submission the additional bleeding patients who have enrolled in the REVERSE-IT trial since the pre-specified interim analysis was completed to support a potential bleeding indication.

- **Presented Positive Results from Phase 2b Trial for Bentracimab:** In April 2022, PhaseBio announced the complete results from its Phase 2b clinical trial of bentracimab and presented these results during a late breaking featured clinical research presentation at the American College of Cardiology's 71st annual scientific session (ACC.22) . The Phase 2b trial was a multi-center, randomized, double-blind, placebo-controlled study, which enrolled a total of 205 older volunteers (50-80 years old), with 154 subjects receiving bentracimab and 51 subjects receiving placebo, after all were pretreated with dual antiplatelet therapy composed of ticagrelor and low-dose aspirin. The primary efficacy endpoint for the Phase 2b trial was reversal of ticagrelor's inhibition of platelet function in actively treated subjects versus placebo as measured using the point-of-care VerifyNow® PRUTest® platelet function assay (VerifyNow). In the Phase 2b trial, bentracimab significantly restored platelet function within five minutes of administration ($p<0.001$), as measured by multiple assays including VerifyNow. The reversal results were tightly correlated across all assays used in the study to measure platelet function. VerifyNow is also the primary measurement used to evaluate efficacy in the ongoing REVERSE-IT Phase 3 trial. These complete safety and efficacy data from the Phase 2b trial are consistent with results from PhaseBio's previously completed Phase 1 trial, conducted in healthy younger volunteers treated with ticagrelor alone and not aspirin, and its Phase 2a trial, conducted in healthy, older (ages 50-80) subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin and with topline results previously announced for the Phase 2b trial on November 3, 2021.

- **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 early in the fourth quarter of 2022.

- **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 March 31, 2022, SFJ has provided funding and paid for amounts on the company's behalf in the aggregate amount of $94.6 million. PhaseBio expects that SFJ will fund or reimburse an additional $25.4 million of clinical trial costs and other expenses.

Quarter Ending Mar. 31, 2022

- Cash and cash equivalents on March 31, 2022, were $18.7 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 $11.1 million, compared to a net loss of $27.4 million for the prior-year period.
- Research and development expense decreased to $14.3 million, as compared to $22.3 million for the same period in 2021. The decrease was primarily attributable to greater drug manufacturing activity in 2021, higher study site startup costs in 2021 related to the Phase 2b trial bentracimab, and higher costs in 2021 related to the Phase 2b trial of pemziviptadil, which was voluntarily ended in the fourth quarter of 2021. The decreases in research and development spending were partially offset by an increase in personnel costs and other costs associated with our general research and development efforts.
- General and administrative expense increased to $4.0 million, compared to $3.3 million for prior-year period.

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 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.
Condensed Balance Sheets
(in thousands)
(unaudited)

	March 31, 2022	December 31, 2021
Assets:		
Cash and cash equivalents	$ 18,688	$ 41,800
Other receivables, prepaid expenses and other current assets	8,881	6,984
Property and equipment, net	9,697	10,230
Operating lease right-of-use assets	1,341	1,469
Other non-current assets	57	57

Total assets	$ 38,664	$ 60,540
Liabilities and stockholders' equity (deficit):		
Current portion of long-term debt	$ 5,425	$ 5,413
Current portion of deferred sublicense revenue	$ 1,594	1,547
Accounts payable, accrued expenses and other current liabilities	14,669	20,923
Long-term debt, net	—	1,359
Operating lease liabilities, net	969	1,073
Deferred sublicense revenue, net	7,458	7,622
Development derivative liability	110,944	114,843
Other long-term liabilities	—	794
Stockholders' equity (deficit)	(102,395)	(93,034)
Total liabilities and stockholders' equity (deficit)	$ 38,664	$ 60,540

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

	Quarter Ended March 31,	
	2022	**2021**
Sublicense Revenue	$ 117	$ —
Operating expenses:		
Research and development	14,336	22,320
General and administrative	4,009	3,327
Total operating expenses	18,345	25,647
Loss from operations	(18,228)	(25,647)
Other expense	7,087	(1,711)
Net loss	$ (11,141)	$ (27,358)
Net loss per common share, basic and diluted	$ (0.23)	$ (0.87)
Weighted average common shares outstanding, basic and diluted	48,635,034	31,282,662

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Source: PhaseBio Pharmaceuticals, Inc.