PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Reports Third Quarter 2019 Financial Results and Recent Corporate Progress

November 14, 2019

Received Written End-of-Phase 1 Meeting Minutes Outlining Clear Development Path for PB2452

Completed Phase 2a Trial of PB2452 in Older and Elderly Subjects on Dual Antiplatelet Therapy

Initiated Registrational Phase 2b Trial of PB2452 in Older and Elderly Subjects on Dual Antiplatelet Therapy

MALVERN, Pa. and SAN DIEGO, Nov. 14, 2019 (GLOBE NEWSWIRE) -- 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 for the third quarter ended September 30, 2019 and provided a corporate update.

“Our recent achievement of several critical milestones exemplifies our focus on execution as we continue the rapid pace of development for our lead program, PB2452,” said Jonathan P. Mow, Chief Executive Officer of PhaseBio. “The advancement of this potentially life-saving therapy from Phase 1 development to registrational studies this year highlights the benefits afforded by Breakthrough Therapy designation and the Accelerated Approval pathway. We believe we remain well positioned to initiate a Phase 3 trial in the first quarter of 2020 in major bleeding and urgent surgical populations to support the submission of a Biologics License Application (“BLA”) for potential accelerated approval of PB2452. With global ticagrelor sales growing 24% year over year in the third quarter of 2019, we continue to see an increasing potential market for PB2452 and are working aggressively to complete the pivotal studies and deliver this therapy to patients in need.”

Third Quarter and Recent Corporate Progress

- **End-of-Phase 1 Meeting update:** In August 2019, PhaseBio announced receipt of written minutes from the PB2452 End-of-Phase 1 (“EOP 1”) meeting with the U.S. Food and Drug Administration (“FDA”) that was held in July 2019. The EOP 1 meeting was focused on gaining alignment with the FDA regarding the clinical and regulatory pathway for potential U.S. approval of PB2452. Based on the FDA’s minutes from the EOP 1 meeting, PhaseBio believes that it has reached general agreement with the FDA on the overall design of a single, non-randomized, open label Phase 3 trial of major bleeding and urgent surgical populations to support the submission of a BLA for potential accelerated approval of PB2452.

- **Completed Phase 2a trial of PB2452:** In September 2019, PhaseBio announced the completion of its Phase 2a trial of PB2452. In the trial, PB2452 achieved immediate and sustained reversal of ticagrelor in older and elderly subjects (ages 50-80) on dual antiplatelet therapy of ticagrelor and low-dose aspirin. PB2452 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. Additionally, based on guidance provided by the FDA during the PB2452 EOP 1 meeting, the Phase 2a trial also investigated a PB2452 regimen for the reversal of supratherapeutic doses of ticagrelor in healthy younger subjects. In the supratherapeutic-dose cohort, PB2452 demonstrated immediate and sustained reversal of ticagrelor and was well tolerated, consistent with the earlier cohorts in the Phase 2a and Phase 1 trials. Based on the preliminary results from this cohort, PhaseBio believes that it has identified an appropriate PB2452 regimen for use in patients who may have supratherapeutic blood levels of ticagrelor as a result of ticagrelor drug-drug interactions or overdosage.

- **Initiated Phase 2b trial of PB2452:** In October 2019, PhaseBio announced that the first patient had been dosed in a Phase 2b clinical trial of PB2452. The Phase 2b multi-center, randomized, double-blind, placebo-controlled trial is designed to evaluate the safety and efficacy of PB2452 in reversing the antiplatelet effects of ticagrelor as part of a dual antiplatelet regimen including low-dose aspirin. Additionally, the Phase 2b trial marks the beginning of FDA-aligned registrational trials to support the submission of a BLA for potential accelerated approval of PB2452. Approximately 200 older and elderly (ages 50-80) subjects are expected to be enrolled, resembling the patient population most likely to be treated with ticagrelor and potentially benefit from PB2452, if approved. Subjects will be randomized in a ratio of 3:1 and will receive either PB2452 or placebo, with approximately 150 subjects receiving PB2452. The primary endpoint of the trial is reversal of the antiplatelet effects of ticagrelor with intravenous infusion of PB2452 or placebo, as measured by the VerifyNow® PRUTest® biomarker.

Upcoming Milestones

- Presentation and publication of full PB2452 Phase 2a results in 1H 2020

- Initiation of Phase 3 trial of PB2452 in 1Q 2020

- Reporting of PB1046 Phase 2b trial results in 2H 2020

Third Quarter 2019 Financial Results

Cash Position

Cash and cash equivalents at September 30, 2019 were $81.8 million, compared to $61.0 million at December 31, 2018. The increase primarily reflects the net proceeds from our underwritten public offering of our common stock in April 2019, partially offset by cash used in operating activities, including the development of our clinical stage programs.

Results of Operations

Three Months Ended September 30, 2019

PhaseBio reported a net loss of $11.4 million for the three months ended September 30, 2019, compared with a net loss of $7.9 million for the same period in 2018. This resulted in a net loss of $0.40 per share for the three months ended September 30, 2019, compared to a net loss of $10.45 per share for the corresponding period in 2018, on both a basic and diluted basis.

Grant revenue was $0.2 million for the three months ended September 30, 2019, as PhaseBio incurred allowable costs qualifying for reimbursement under the government grants. PhaseBio recorded $0.4 million of grant revenue for the same period in 2018.

Research and development expense increased to $9.0 million for the three months ended September 30, 2019, as compared to $4.4 million for the three months ended September 30, 2018, reflecting increased costs associated with preclinical and clinical development activities largely related to PB2452 and increased personnel costs.

General and administrative expense increased to $2.8 million for the three months ended September 30, 2019, compared to $1.1 million for the three months ended September 30, 2018, primarily attributable to increases in professional services including legal, marketing and other consulting services, personnel expense due to additional headcount and expenses associated with being a public company.

About PB2452

PB2452 is a novel, recombinant, human monoclonal antibody antigen-binding fragment designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. In a Phase 1 clinical trial, PB2452 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 antiplatelet drugs. The Phase 1 clinical trial of PB2452 in healthy volunteers was published in the *New England Journal of Medicine* in March 2019.[1] In April 2019, PB2452 received Breakthrough Therapy designation from the FDA. Breakthrough Therapy designation may be granted by FDA when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapy. PhaseBio plans to initiate a single pivotal Phase 3 clinical trial of PB2452 in the first quarter of 2020 to support a BLA for PB2452 in both major bleeding and urgent surgery indications. There are currently no approved reversal agents for ticagrelor or any other antiplatelet drugs.

About PhaseBio

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies to treat cardiopulmonary diseases. The company's lead development candidate is PB2452, a novel reversal agent for the antiplatelet therapy ticagrelor. PhaseBio is also leveraging its proprietary elastin-like polypeptide ("ELP") technology platform to develop therapies with the potential for less-frequent dosing and improved pharmacokinetics. PhaseBio's second product candidate PB1046, which is based on ELP, is a once-weekly vasoactive intestinal peptide receptor agonist for the treatment of pulmonary arterial hypertension.

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 conduct or timing of our clinical trials and our research, development and regulatory plans for PB2452, PB1046 and our ELP research programs. 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, 2019. These forward-looking statements speak only as of the date thereof, 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)

	September 30, 2019	December 31, 2018
Assets:		
Cash and cash equivalents	$ 81,771	$ 61,031
Other receivable, prepaid expenses and other current assets	1,598	1,597
Property and equipment, net	1,022	355
Operating lease right-of-use assets	1,780	—

Other non-current assets	32	43
Total assets	$ 86,203	$ 63,026
Liabilities and stockholders' equity:		
Current portion of long-term debt	$ 1,990	$ —
Accounts payable, accrued expenses and other current liabilities	3,972	4,577
Long-term debt	7,740	7,500
Operating lease liabilities	1,577	—
Other long-term liabilities	120	—
Deferred rent	—	22
Stockholders' equity	70,804	50,927
Total liabilities and stockholders' equity	$ 86,203	$ 63,026

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Grant revenue	$ 241	$ 411	$ 1,097	$ 411
Revenue under collaborative agreement	—	—	500	—
Total revenue	241	411	1,597	411
Operating expenses:				
Research and development	9,028	4,354	22,530	9,779
General and administrative	2,803	1,056	7,523	2,616
Total operating expenses	11,831	5,410	30,053	12,395
Loss from operations	(11,590)	(4,999)	(28,456)	(11,984)
Other income (expense)	199	(2,902)	540	(6,994)
Net loss	$ (11,391)	$ (7,901)	$ (27,916)	$ (18,978)
Net loss per common share, basic and diluted	$ (0.40)	$ (10.45)	$ (1.03)	$ (25.33)
Weighted average common shares outstanding, basic and diluted	28,719,932	755,908	27,065,774	749,198

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Source: PhaseBio Pharmaceuticals, Inc.