

BiomX Reports Third Quarter 2022 Financial Results and Provides Business Update

Continued Progress Enrolling Patients in Phase 1/2 Trial of BX004 for Treatment of Lung Infections in Cystic Fibrosis; Results from Part 1 of the Trial Now Expected in Q1 2023

Announced Publication in Cell of Research Demonstrating Proof-of-Concept Assessment of Orally Administered Phage Treatment in Preclinical Model of Inflammatory Bowel Disease

Cash Runway Through at Least Mid-2024

Company Will Host a Conference Call and Webcast Today at 8:00 am ET

NESS ZIONA, Israel, Nov. 09, 2022 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage microbiome company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the third quarter ended September 30, 2022.

"Despite encountering challenges early in the quarter in recruiting cystic fibrosis patients following the COVID-19 pandemic, we have recently put in place important mechanisms to accelerate screening and enrollment and are encouraged by the recent increased enrollment into BX004 that will impact both parts of the trial," said **Jonathan Solomon**, Chief Executive Officer of BiomX. "Based on these latest trends, we now anticipate that enrollment for Part 1 of the study will be complete by year-end. Factoring in a modest impact from the U.S. holiday season and the time required for data analysis following each patient's treatment period, we now expect to announce results from Part 1 of the trial in the first quarter of 2023, followed by results from Part 2 in the third quarter of 2023. We believe that we remain financially and operationally positioned to execute on our business plan with respect to our CF program, with cash runway anticipated to take us through at least mid-2024. We appreciate the continued support of our shareholders and look forward to providing our initial data from the CF program."

Clinical Program Updates

Cystic Fibrosis (BX004)

- BiomX has dosed the first patients in the Company's Phase 1b/2a study evaluating BX004 for the treatment of chronic respiratory infections in patients with cystic fibrosis ("CF").
- BX004 is being developed for the treatment of chronic respiratory infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients

with CF.

- The Phase 1b/2a trial is composed of two parts. Part 1 of the study will evaluate the safety, pharmacokinetics, and microbiologic/clinical activity of BX004 in eight CF patients in a single ascending dose and multiple dose design, with results expected in the first quarter of 2023. Part 2 of the study will evaluate the safety and efficacy of BX004 in 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 are expected in the third quarter of 2023.
- As previously announced, BiomX has received a Therapeutics Development Award of up to \$5 million from the Cystic Fibrosis Foundation ("CF Foundation"). The award is structured as an equity investment in which the CF Foundation has agreed to purchase up to \$5 million of BiomX common stock across two separate tranches. The first tranche was received on December 21, 2021, with the CF Foundation making an initial equity investment of \$3 million. Upon completion of all patient dosing in Part 1 of the Company's Phase 1b/2a study of BX004, BiomX would have the right to receive the second tranche of \$2 million, also as an equity investment.

Atopic Dermatitis (BX005)

• The Company is collaborating with Maruho Co. Ltd., a leading dermatology-focused pharmaceutical company in Japan, supporting a range of pre-clinical activities to move this program forward, and working on evaluating timelines for a clinical trial.

RECENT CORPORATE HIGHLIGHTS

 In August, the Company announced the publication of a scientific paper titled "Targeted suppression of human IBD-associated gut microbiota commensals by phage consortia for treatment of intestinal inflammation" in the journal, Cell. The research was conducted across several organizations, including BiomX and the Weizmann Institute of Science, and presents phage proof of concept in preclinical models of inflammatory bowel disease as well as highlights from the clinical study. The paper is available online at https://www.cell.com/cell/fulltext/S0092-8674(22)00850-9.

Third Quarter 2022 Financial Results

- Cash balance, short-term deposits and restricted cash as of September 30, 2022, were \$41.5 million, compared to \$63.1 million as of December 31, 2021. The decrease was primarily due to net cash used in operating activities. Based upon the Company's strategic focus on the CF program, the existing cash and cash equivalents are expected to be sufficient to fund the current operating plan until at least the middle of 2024.
- Research and development expenses, net were \$3.5 million for the three months ended September 30, 2022, compared to \$6.6 million for the same period in 2021. The decrease is primarily due to a decrease in salaries and related expenses and stock-based compensation expenses driven by a reduction in personnel, as part of the corporate restructuring the Company announced in May of this year, as well as pausing the development of BX003, the product candidate for the treatment of Inflammatory Bowel Disease and Primary Sclerosing Cholangitis, pausing the development of the Company's colorectal cancer product candidate, and the discontinuation of the Company's product candidate for the treatment of acne, BX001. The decrease was partially offset by a decrease in grants from the Israel Innovation

Authority.

- **General and administrative expenses** were \$2.6 million for the three months ended September 30, 2022, compared to \$2.8 million for the same period in 2021. The decrease is primarily due to a decrease in salaries and related expenses and stock-based compensation expenses due to a reduction in workforce.
- **Net loss** for the third quarter of 2022 was \$6.8 million, compared to \$10 million for the same period in 2021.
- Net cash used in operating activities for the nine months ended September 30, 2022 was \$21.9 million, compared to \$18.5 million for the same period in 2021.

Conference Call and Webcast Information

BiomX management will host a conference call and webcast today at 8:00 am ET to report financial results and business updates for the third quarter 2022. To participate in the conference, please dial 1-877-407-0724 (U.S.), 1-809-406-247 (Israel), or 1-201-389-0898 (International). A live and archived webcast of the call will be available on the Investors section of the Company's website at <u>www.biomx.com</u>.

About BiomX

BiomX is a clinical-stage microbiome company developing both natural and engineered phage cocktails designed to target and destroy bacteria in the treatment of chronic diseases. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at <u>www.biomx.com</u>, the content of which does not form a part of this press release.

Safe Harbor

This press release contains express or implied "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. For example, when BiomX discusses future updates on its CF and Atopic Dermatitis programs, its expectations regarding the timing of the completion of enrollment and results of the CF trial, the potential safety, tolerability and potential treatment effect of its product candidates, the potential to achieve the applicable clinical milestones required to receive an additional \$2 million investment from CFF, and its cash runway and financial and operational position, BiomX is making forward-looking statements. Forwardlooking statements are neither historical facts nor assurances of future performance. Instead, they are based only on BiomX management's current beliefs, expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of BiomX's control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, investors should not rely on any of these forward-looking statements and should review the risks and uncertainties described under the caption "Risk Factors" in BiomX's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 30, 2022 and additional disclosures BiomX makes in its other filings with the SEC, which are available on the SEC's website at <u>www.sec.gov</u>. Forward-looking statements are made as of the date of this press release, and except as provided by law BiomX expressly disclaims any obligation or undertaking to update forward-looking statements.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (USD in thousands, except share and per share data) (unaudited)

		Three Mon Septem		Nine Months Ended September 30,	
	Note	2022	2021	2022	2021
Research and development expenses, net Amortization of intangible assets General and administrative expenses Operating loss		3,536 380 <u>2,633</u> 6,549	6,608 380 <u>2,845</u> 9,833	13,049 1,139 <u>7,471</u> 21,659	16,102 1,139 <u>8,436</u> 25,677
Other income Interest expenses Financial expenses (income), net		(52) 555 (280)	172	(52) 1,504 (706)	172
Loss before tax		6,772	10,021	22,405	25,753
Tax expenses		8	10	26	16
Net loss		6,780	10,031	22,431	25,769
Basic and diluted loss per share of Common Stock	6	0.23	0.37	0.75	1.03
Weighted average number of shares of Common Stock outstanding, basic and diluted		29,907,812	27,077,903	29,812,542	25,120,037

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CONDENSED CONSOLIDATED BALANCE SHEETS (USD in thousands, except share and per share data) (unaudited)

		As of		
		September 30,		
100570	Note	2022	2021	
ASSETS				
Current assets				
Cash and cash equivalents		37,067	62,099	
Restricted cash		960	996	
Short-term deposits		3,500	-	
Other current assets		1,003	3,543	
Total current assets		42,530	66,638	
Property and equipment, net		5,034	5,694	
Intangible assets, net		382	1,519	
Operating lease right-of-use assets		3,955	4,139	
Total non-current assets		9,371	11,352	
		51,901	77,990	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Trade accounts payable		1,781	2,795	
Other accounts payable		2,023	5,453	
Contract liability		-	1,976	
Current portion of operating lease liabilities		687	819	
Current portion of long-term debt	4	2,989	-	
Total current liabilities		7,480	11,043	
Non-current liabilities				
Contract liability		1,976	-	
Long-term debt, net of current portion	4	11,799	14,410	
Operating lease liabilities, net of current portion		3,882	4,787	
Other liabilities		206	215	
Total non-current liabilities		17,863	19,412	
Commitments and Continuousies	0			

Commitments and Contingencies

Stockholders' equity

Preferred Stock, \$0.0001 par value; Authorized -1,000,000 shares as of September 30, 2022 and December 31, 2021. No shares issued and outstanding as of September 30, 2022 and December 31, 2021. -Common Stock, \$0.0001 par value; Authorized -120,000,000 shares as of September 30, 2022 and 60,000,000 shares as of December 31, 2021. Issued - 29,982,282 shares as of September 30, 2022 and 29,753,238 shares as of December 31, 2021. Outstanding – 29,976,582 shares as of September 30, 2022 and 29,747,538 shares as of December 31, 2021. 2

Additional paid in capital	157,471	156,017
Accumulated deficit	(130,915)	(108,484)
Total stockholders' equity	26,558	47,535
	51,901	77,990

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Source: BiomX Inc.



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