

November 15, 2021



BiomX Reports Third Quarter 2021 Financial Results and Provides Business Update

Announces Strategic Focus on Cystic Fibrosis and Atopic Dermatitis Programs Based on Potential Proof-of-Concept Clinical Data Readouts in 2022

Cash Runway Now Extended to End of 2023, Well Beyond Key 2022 Data Readouts

FDA Clears BiomX to Begin Phase 1b/2a Trial in Cystic Fibrosis; Trial to Start Imminently

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

BRANFORD, Conn. and NESS ZIONA, Israel, Nov. 15, 2021 (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, reported today financial results and provided a business update for the third quarter ended September 30, 2021.

"In planning for the years ahead, BiomX has made the decision to prioritize the development of our cystic fibrosis and atopic dermatitis product candidates, as each has the potential to generate proof-of-concept clinical data readouts in 2022. BiomX will also discontinue development of its acne program," said Jonathan Solomon, Chief Executive Officer of BiomX. "We believe that by focusing on the efficient use of BiomX's capital on selected programs that can generate clinically meaningful, proof-of-concept data, will best position our company to drive value creation for shareholders. With this decision, we intend to also postpone our development efforts temporarily in inflammatory bowel disease and colorectal cancer until 2023.

"Importantly, our new strategic focus will have a positive impact on our balance sheet. This new focus may allow us to extend our cash runway by up to 6 months, until at least the end of 2023, and additional tranches that may become available to us under our venture debt facility upon satisfaction of certain specified milestones may further extend our cash runway to the first half of 2024." We therefore believe that we remain well-positioned financially through our expected clinical data readouts in cystic fibrosis and atopic dermatitis."

RECENT CORPORATE HIGHLIGHTS

- In October 2021, BiomX reported topline results of the cosmetic Phase 2 acne study showing statistically significant improvement from baseline observed in the appearance of acne-prone skin but with no meaningful difference demonstrated for BX001 relative to vehicle.
- In October 2021, BiomX entered into an agreement with Maruho Co. Ltd., Japan's

largest dermatology-focused pharmaceutical company, for a right of first offer to license BiomX's atopic dermatitis product candidate, BX005, in Japan. The right of first offer will commence following the availability of results from the Phase 1/2 study of BX005 expected in 2022. Maruho also entered into a binding agreement for an equity investment in BiomX, intended primarily to support the Phase 1/2 study, of \$3 million at a premium to the market share price.

- In September 2021, BiomX was cleared by the U.S. Food and Drug Administration (FDA) to initiate a Phase 1b/2a trial of BX004 in cystic fibrosis patients with chronic respiratory infections caused by *Pseudomonas aeruginosa*.
- In August 2021, the Company announced that it entered into a debt financing agreement of up to \$30 million with Hercules Capital, Inc. (NYSE:HTGC). In July 2021, BiomX announced it raised \$15 million in a registered direct offering of common stock and warrants.

Clinical Program Updates

Cystic Fibrosis (“CF”) (BX004)

- 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.
- In September 2021, BX004 was cleared by the FDA to initiate a Phase 1b/2a trial in CF patients with chronic respiratory infections caused by *Pseudomonas aeruginosa*.
- The Phase 1b/2a trial is composed of two parts and is expected to start imminently. Part 1 of the trial 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 second quarter of 2022. Part 2 of the trial 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 by the third quarter of 2022.

Atopic Dermatitis (“AD”) (BX005)

- BX005 is designed to shift the skin microbiome composition of AD patients to its “pre-flare” state by reducing *Staphylococcus aureus* burden, potentially resulting in clinical improvement.
- BX005 is currently in the final stages of GMP production. Due to delays in communications with the FDA attributable to COVID-related matters, the Company now expects results from its Phase 1/2 proof-of-concept trial evaluating the safety and efficacy of BX005 in the third quarter of 2022 instead of the first half of 2022.

Inflammatory Bowel Disease (“IBD”) and Colorectal Cancer Programs

- Consistent with the new strategic focus on CF and AD programs and the efficient deployment of BiomX capital, the Company plans to temporarily pause its development efforts in IBD and colorectal cancer until early 2023, as neither program would otherwise be expected to yield proof-of-concept data in patients through the end

of 2022.

Acne-Prone Skin (BX001)

- Based upon the topline results of the cosmetic Phase 2 acne trial previously announced in October 2021, the Company has now determined that it is discontinuing this program to focus resources on the CF and AD programs.

Third Quarter 2021 Financial Results

- **Cash balance and short-term deposits** as of September 30, 2021, were \$68.3 million, compared to \$57.1 million as of December 31, 2020. The increase was primarily due to net cash provided by financing activities partially offset with net cash used in operating activities. During the third quarter, the Company completed a \$15 million registered direct equity financing and debt financing agreement of up to \$30 million. Based upon the BiomX's new strategic focus on its cystic fibrosis and atopic dermatitis programs, the Company now expects its existing cash, cash equivalents and short-term deposits to be sufficient to fund the Company's current operating plan until the end of 2023. Additional tranches that will become available to the Company under its venture debt facility upon satisfaction of certain specified milestones can further extend the Company's cash runway to the first half of 2024.
- **Research and development (R&D) expenses, net** were \$6.6 million for the three months ended September 30, 2021, compared to \$6.1 million for the same period in 2020. The increase was primarily due to increased expenses related to conducting pre-clinical and clinical trials of our product candidates and an increase in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees in R&D and clinical activities.
- **General and administrative expenses** were \$2.8 million for the three months ended September 30, 2021, compared to \$2.4 million for the same period in 2020. The increase was primarily due to increases in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees, due to an increase in expenses associated with operating as a public company, such as directors' and officers' insurance and due to expenses resulted from moving into new premises.
- **Net loss** for the third quarter of 2021 was \$10.0 million, compared to \$8.8 million for the same period in 2020.
- **Net cash used in operating activities** for the nine months ended September 30, 2021 was \$18.5 million, compared to \$17.3 million for the same period in 2020.

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 2021 ended September 30, 2021. 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 www.biomx.com.

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, such as cystic fibrosis, atopic dermatitis, inflammatory bowel disease, primary sclerosing cholangitis, and colorectal cancer. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at www.biomx.com, 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 its expectations regarding the sufficiency of cash, cash equivalents and short-term deposits to fund the Company’s current operating plan until at least the end of 2023, or even later, the ability of its products to address unmet medical needs, the potential to receive up to \$15 million in additional loan tranches if certain milestones are met, the design, aim, expected timing and results of its preclinical and clinical trials and studies, including resumption of certain development programs, as well as its pipeline and the potential of its product candidates, BiomX is making forward-looking statements. Forward-looking 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 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 31, 2021 and additional disclosures BiomX makes in its other filings with the SEC, which are available on the SEC’s website at www.sec.gov. 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.

BIOMX INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

USD in thousands, except share and per share data

		Three Months Ended September 30,		Nine Months Ended September 30,	
	Note	2021	2020	2021	2020
Research and development ("R&D") expenses, net		608,6	6,056	102,16	13,302
Amortization of intangible assets		380	380	1,139	1,139
General and administrative expenses		2,845	2,394	8,436	6,749
Operating loss		9,833	8,830	25,677	21,190
Financial expenses (income), net		188	5	76	(248)
Loss before tax		021,10	8,835	753,25	20,942
Tax expenses		10	-	16	-
Net Loss		031,10	8,835	769,25	20,942
Basic and diluted loss per share of Common Stock	6	0.37	0.38	1.03	0.91

Weighted average number
of shares of Common Stock
outstanding, basic and
diluted

27,077,903	23,150,253	25,120,037	23,013,790
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BIOMX INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

USD in thousands

	As of		
	Note	September 30, 2021	December 31, 2020
ASSETS			
Current assets			
Cash and cash equivalents		67,346	36,477
Restricted cash		985	763
Short-term deposits		-	19,851
Other current assets		467,1	3,576
Total current assets		798,69	60,667
Property and equipment, net		5,863	2,228
Intangible assets, net		1,899	3,038

Operating lease right-of-use assets	4,239	4,430
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Total non-current assets	12,001	9,696
	<hr/>	<hr/>
	8799,1	70,363

As of

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Note	September 30, 2021	December 31, 2020
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LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Trade account payables	1,879	2,320
Other account payables	321,6	3,978
Current portion of operating lease liabilities	799	863
	<hr/>	<hr/>
Total current liabilities	8,999	7,161

Non-current liabilities

Long-term debt	4	14,225	-
Operating lease liabilities, net of current portion		4,728	5,032
Other liabilities		420	701
		<hr/>	<hr/>

Total non-current liabilities		19,373	5,733
Commitments and Collaborations	3		
Stockholders' equity	5		
Preferred Stock, \$0.0001 par value; Authorized - 1,000,000 shares as of September 30, 2021 and December 31, 2020. No shares issued and outstanding as of September 30, 2021 and December 31, 2020.		-	-
Common Stock, \$0.0001 par value; Authorized - 60,000,000 shares as of September 30, 2021 and December 31, 2020. Issued – 28,206,229 shares as of September 30, 2021 and 23,270,337 shares as of December 31, 2020. Outstanding – 28,200,529 shares as of September 30, 2021 and 23,264,637 shares as of December 31, 2020.		3	2
Additional paid in capital		151,451	129,725
Accumulated deficit		(9027,8)	(72,258)
Total stockholders' equity		5427,3	57,469
		81,799	70,363

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Source: BiomX Inc



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