May 21, 2024

BiomX Reports First Quarter 2024 Financial Results and Provides Business and Program Updates

Following merger with Adaptive Phage Therapeutics in March, combined company reports funding sufficient to support important data readouts for lead clinical programs in 2025

Company will host a conference call and webcast today at 8:00 am ET

GAITHERSBURG, Md. and NESS ZIONA, Israel, May 21, 2024 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided business and program updates for the first quarter ended March 31, 2024. BiomX is announcing merged financial reporting for the first time following the closing of its merger with Adaptive Phage Therapeutics, Inc. ("APT") in March 2024 and a concurrent $50 million private placement.

Based on a cash balance, short term deposits and restricted cash of $44.1 million as of March 31, 2024, BiomX estimates it currently has a cash runway through the fourth quarter of 2025. The Company anticipates data readouts for both of its lead programs in 2025: Topline results (through Week 13) for the Phase 2 study of BX211, a personalized phage treatment for the treatment of diabetic foot osteomyelitis ("DFO") associated with *Staphylococcus aureus* (*S. aureus*), are expected in the first quarter of 2025, and Phase 2b trial results for BX004, a fixed multi-phage cocktail for the treatment of cystic fibrosis ("CF") patients with chronic pulmonary infections caused by *Pseudomonas aeruginosa* (*P. aeruginosa*), are expected in the third quarter 2025.

"With the recent merger with APT and our private placement, we believe we have entered into a new era for BiomX as a leading phage company focused on treating harmful bacteria underlying serious chronic infections," said Jonathan Solomon, Chief Executive Officer of BiomX. "BiomX is rapidly advancing a pipeline with two lead candidates, both expecting Phase 2 readouts next year. For BX004, we have demonstrated for the first time in a randomized controlled study that a subset of CF patients converted to sputum culture negative for *P. aeruginosa* after only 10 days of treatment with BX004[1]. These findings were showcased in a presentation that was selected as a 'Top Poster' at last month's ESCMID Global Congress. With the APT merger, we now have added BX211, a promising treatment for DFO, advancing in a Phase 2 study with more than 70% of patients enrolled. On the business side, we have gained important and accredited life sciences investors, another important validation for the potential of phage therapy as a new therapeutic modality and the strength of our lead candidates. We believe these and other recent achievements are bringing us closer to our goal of meeting unmet patient needs through advancement of our phage-based therapies."

Business Update

- In March 2024, the Company announced the closing of its merger with APT and concurrent closing of a private placement financing with $50 million of gross proceeds led by top institutional healthcare investors, including affiliates of Deerfield Management and the AMR Action Fund, and additional investors including the Cystic Fibrosis Foundation, OrbiMed, and Nantahala Capital Management. The net proceeds from the private placement are primarily being used to further advance BiomX's lead product candidates, BX004 and BX211.

Clinical Program Updates

Cystic Fibrosis (BX004)

- In January 2024, the Company announced that BX004 was granted Orphan Drug Designation by the United States Food and Drug Administration ("FDA"), for the treatment of chronic pulmonary infection caused by *P. aeruginosa* in patients with CF.
- In April 2024, the Company presented at this year's European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Global Congress positive safety and efficacy results from Part 2 of the Phase 1b/2a trial evaluating the Company's novel phage cocktail, BX004, for the treatment of chronic pulmonary infections caused by *P. aeruginosa* in CF patients. BiomX's poster was selected as a "Top Poster", ranking it among the 1-2% of top-rated abstracts in the category submitted and accepted at the ESCMID Global Congress.
- Highlights from the Part 2 data of the Phase 1b/2a study included:
    - Study drug was safe and well-tolerated, with no related SAEs (serious adverse events) or related APEs (acute pulmonary exacerbations) to study drug.
    - In the BX004 arm, 3 out of 21 (14.3%) patients converted to sputum culture negative for *P. aeruginosa* after 10 days of treatment (including 2 patients after 4 days) compared to 0 out of 10 (0%) in the placebo arm[1]. BX004 vs. placebo showed a clinical effect in a predefined subgroup of patients with reduced baseline lung function (FEV1<70%). Difference between groups at Day 17: relative FEV1 improvement of 5.67% (change from baseline +1.46 vs. -4.21) and +8.87 points in CFQR respiratory symptom scale (change from baseline +2.52 vs. -6.35).

Diabetic Foot Osteomyelitis (BX211)

- BX211 is a personalized phage treatment that BiomX is now developing following the merger with APT. BX211 is being developed for the treatment of DFO associated with *S. aureus*. The safety, tolerability, and efficacy of BX211 is currently being evaluated in a randomized, double-blind, placebo-controlled, multi-center Phase 2 trial for subjects with DFO. Target enrollment for the study is 45 patients, and to date, more than 70% of the patients have been enrolled. Initial topline results of the Phase 2 trial are expected in the first quarter of 2025. Study design was guided in part by experience with numerous compassionate cases using phage therapy for the treatment of DFO and Osteomyelitis.

First Quarter 2024 Financial Results

The financial results of the first quarter of 2024 include the consolidation of the financial results of APT from the closing date of the merger and the accounting implications derived from the merger and the concurrent private placement.

- **Cash balance, short-term deposits and restricted cash** as of March 31, 2024, were $44.1 million, compared to $30.3 million as of March 31, 2023. The increase was primarily due to the private placement, which was partially offset by net cash used in operating activities and the repayment of a debt facility in March 2024. The Company estimates its cash, cash equivalents and short-term deposits are sufficient to fund its operations through the fourth quarter of 2025.
- **Research and development expenses, net** were $4.1 million for the first quarter of 2024, compared to $4.6 million for the first quarter of 2023. The decrease is primarily due to the completion of the CF clinical trial, and was partially offset by lower grants payments from the Israeli Innovation Authority and R&D expenses related to APT that were incurred after the merger.
- **General and administrative expenses** were $2.7 million for the first quarter of 2024, compared to $1.6 million for the first quarter of 2023. The increase primarily resulted from expenses related to the merger with APT and the concurrent private placement.
- **Net loss** was $17.3 million for the first quarter of 2024, compared to $6.4 million for the first quarter of 2023. The increase is mainly due to changes in fair value of private placement warrants that were issued in this quarter.
- **Net cash used in operating activities** for the three months ended March 31, 2024, was $11.4 million, compared to $5.0 million for the same period in 2023.

Conference Call and Webcast Details
BiomX will host a conference call and webcast on May 21, 2024, at 8:00 a.m. ET to discuss its first quarter 2024 financial results and to provide a corporate update.

Conference Call Dial-In Information:

Participant Dial-In Number:	+1 877-407-0724
Participant International Dial-In	+1 201-389-0898
Webcast:	Link

About BX004
BiomX is developing BX004, a fixed multi-phage cocktail, for the treatment of CF patients with chronic pulmonary infections caused by *P. aeruginosa*, a main contributor to morbidity and mortality in patients with CF. In November 2023, BiomX announced positive topline results from Part 2 of the Phase 1b/2a trial where BX004 demonstrated improvement in pulmonary function associated with a reduction in *P. aeruginosa* burden compared to placebo in a predefined subgroup of patients with reduced lung function (baseline FEV1<70%).

BiomX expects to initiate a randomized, double blind, placebo-controlled, multi-center Phase 2b trial in CF patients with chronic *P. aeruginosa* pulmonary infections in the fourth quarter of 2024. The trial is designed to enroll approximately 60 patients randomized at a 2:1 ratio to BX004 or placebo. Treatment is expected to be administered via inhalation twice daily for a duration of 8 weeks. The trial is designed to monitor the safety and tolerability of BX004 and

is designed to demonstrate improvement in microbiological reduction of *P. aeruginosa* burden and evaluation of effects on clinical parameters such as lung function measured by FEV1 and patient reported outcomes. Trial results are expected in the third quarter 2025. The FDA has granted BX004 Fast Track designation and Orphan Drug Designation.

About BX211
BX211 is a personalized phage treatment for the treatment of DFO associated with *S. aureus*. The personalized phage treatment tailors a specific phage selected from a proprietary phage-bank according to the specific strain of *S. aureus* biopsied and isolated from each patient. DFO is a bacterial infection of the bone that usually develops from an infected foot ulcer and is a leading cause of amputation in patients with diabetes.

The ongoing randomized, double-blind, placebo-controlled, multi-center Phase 2 trial investigating the safety, tolerability, and efficacy of BX211 for subjects with DFO associated with *S. aureus* is expected to enroll approximately 45 subjects randomized at a 2:1 ratio to BX211 or placebo. BX211 or placebo is designed to be administered weekly, by topical and IV route at Week 1 and by the topical route only at each of Weeks 2-12. Over the 12-week treatment period, all subjects are expected to continue to be treated in accordance with standard of care which will include antibiotic treatment as appropriate. A first readout of study topline results is expected at Week 13 evaluating healing of the wound associated with osteomyelitis, followed by a second readout at Week 52 evaluating amputation rates and resolution of osteomyelitis based on X-ray, clinical assessments, and established biomarkers (ESR and CRP). These readouts are expected in the first quarter of 2025 and the first quarter of 2026, respectively.

About BiomX
BiomX is a clinical-stage company leading the development of natural and engineered phage cocktails and personalized phage treatments designed to target and destroy harmful bacteria for the treatment of chronic diseases with substantial unmet needs. BiomX discovers and validates proprietary bacterial targets and applies its BOLT (“BacteriOphage Lead to Treatment”) platform to customize phage compositions against these targets. For more information, please visit 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 the expected timing of clinical trials, key data readouts and topline results, its cash runway and sufficiency of capital to meet milestones and the potential benefits of BX004 and BX211, 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. In addition, past and current pre-clinical and clinical results, as well as compassionate use, are not indicative and do not guarantee future success of BiomX clinical trials. 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, as a result of various important factors, including risks and uncertainties related to the ability to recognize the anticipated benefits of the merger with APT; the outcome of any legal proceedings that may be instituted against BiomX following the merger and related transactions; the ability to obtain or maintain the listing of the common stock of BiomX on the NYSE American following the merger; costs related to the merger; changes in applicable laws or regulations; the possibility that BiomX may be adversely affected by other economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in BiomX's drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies and early clinical trials may not be replicated in later clinical trials, BiomX's ability to enroll patients in its clinical trials, and the risk that any of its clinical trials may not commence, continue or be completed on time, or at all; decisions made by the FDA and other regulatory authorities; investigational review boards at clinical trial sites and publication review bodies with respect to our development candidates; BiomX's ability to obtain, maintain and enforce intellectual property rights for its platform and development candidates; its potential dependence on collaboration partners; competition; uncertainties as to the sufficiency of BiomX's cash resources to fund its planned activities for the periods anticipated and BiomX's ability to manage unplanned cash requirements; and general economic and market conditions. 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 April 4, 2024, 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.
Assaf Oron
+97254-2228901
assafo@biomx.com

[1] In patients that had quantitative CFU levels at study baseline

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

	As of	
	March 31, 2024	**December 31, 2023**
ASSETS		

Current assets		
Cash and cash equivalents	43,007	14,907
Restricted cash	1,108	957
Other current assets	2,986	1,768
Total current assets	47,101	17,632
Non-current assets		
Operating lease right-of-use assets	11,279	3,495
Property and equipment, net	7,438	3,902
In-process Research and development ("IPR&D") assets and Goodwill	15,788	-
Total non-current assets	34,505	7,397
	81,606	25,029

	As of	
	March 31, 2024	**December 31, 2023**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade accounts payable	3,686	1,381
Current portion of lease liabilities	985	666
Other accounts payable	6,036	3,344
Current portion of long-term debt	-	5,785
Total current liabilities	10,707	11,176
Non-current liabilities		
Contract liability	1,976	1,976
Long-term debt, net of current portion	-	5,402
Operating lease liabilities, net of current portion	9,139	3,239
Other liabilities	153	155
Private Placement Warrants	36,755	-
Total non-current liabilities	48,023	10,772
Commitments and Contingencies (Note 7)		
Redeemable Convertible Preferred Shares		

Preferred Stock, $0.0001 par value; Authorized - 1,000,000 shares as of March 31, 2024 and December 31, 2023. Issued and outstanding- 256,887 as of March 31, 2024. No shares issued and outstanding as of December 31, 2023.	32,420	-
Stockholders' equity (Capital Deficiency)		
Common Stock, $0.0001 par value; Authorized - 120,000,000 shares as of March 31, 2024 and December 31, 2023. Issued and outstanding-59,998,342 shares as of March 31, 2024 and 45,979,930 shares as of December 31, 2023.	4	3
Additional paid in capital	170,749	166,048
Accumulated deficit	(180,297)	(162,970)
Total stockholders' equity (Capital Deficiency)	(9,544)	3,081
	81,606	25,029

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

	Three Months Ended March 31,	
	2024	**2023**
Research and development ("R&D") expenses, net	4,105	4,564
General and administrative expenses	2,680	1,644
Operating loss	6,785	6,208
Other income	(88)	(91)
Interest expenses	850	565
Loss from change in fair value of Private Placement Warrants	8,010	-
Finance expense (income), net	1,765	(327)
Loss before tax	17,322	6,355
Tax expenses	5	6
Net loss	17,327	6,361

Basic and diluted loss per share of Common Stock	0.28	0.20
Weighted average number of shares of Common Stock outstanding, basic and diluted	62,292,277	32,125,227

Source: BiomX