

# BiomX Announces Entry into Merger Agreement with Adaptive Phage Therapeutics and Concurrent \$50 Million Financing

Acquisition will create phage therapy company with an advanced pipeline with twoPhase 2 assets, BX004 for the treatment of chronic pulmonary infections in cystic fibrosis ("CF") patients and BX211 for the treatment of diabetic foot osteomyelitis ("DFO")

Concurrently with entering into the definitive merger agreement, BiomX entered into a definitive agreement for a private placement financing of \$50 million that will be used to advance two lead product candidates through Phase 2 clinical readouts in 2025

Conference call today at 00:9 a.m. EST

CAMBRIDGE, Mass. and NESS ZIONA, Israel, March 06, 2024 (GLOBE NEWSWIRE) --BiomX Inc. (NYSE American: PHGE) (together with its subsidiaries and/or associates, "BiomX"), a clinical-stage company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today announced that it has entered into a definitive merger agreement with Adaptive Phage Therapeutics, Inc. ("APT"), a U.S.-based privatelyheld, clinical-stage biotechnology company pioneering the development of phage-based therapies to combat bacterial infections (the "Acquisition"). Immediately after the effective time of the Acquisition, and before giving effect to the concurrent private placement the former stockholders of BiomX will own approximately 55% and the former stockholders of APT will own approximately 45% of the consolidated entity of BiomX and APT. The Acquisition is expected to close within the next 30 days, subject to the satisfaction of the closing conditions described in the definitive merger agreement. Concurrently with entering into the definitive merger agreement, BiomX entered into a definitive purchase agreement for the sale of shares of newly created non-voting convertible preferred stock ("Series X Preferred Stock") and warrants to purchase shares of BiomX common stock in a private placement to certain institutional accredited investors led by affiliates of Deerfield Management Company and the AMR Action Fund, and additional investors including the Cystic Fibrosis Foundation, OrbiMed and Nantahala Capital. The private placement is expected to result in gross proceeds to BiomX of \$50 million before deducting placement agent and other offering expenses. The proceeds from the private placement are expected to provide funding through the results from a planned Phase 2b trial that will evaluate BiomX's lead product candidate, BX004, for the treatment of chronic pulmonary infections caused by Pseudomonas aeruginosa (P. aeruginosa) in CF patients expected in the third guarter of 2025 and Phase 2 results from APT's clinical-stage product candidate, now named BX211, for the treatment of Staphylococcus aureus (S. aureus) infections in DFO patients expected in the first guarter of 2025. The private placement is expected to close substantially concurrently with, and subject to the closing of, the Acquisition.

"BiomX's acquisition of APT will create a leading phage company with diverse technologies and an advanced clinical pipeline," said Jonathan Leff, Partner and Chairman of the Deerfield Institute at Deerfield Management. "With important data readouts for two programs expected in 2025, the funding from this transaction is designed to provide multiple opportunities to create stockholder value by reaching critical inflection points in each program's clinical development."

"Today's announcement sends a clear vote of confidence from leading biotechnology investors who led this transaction that phage technology holds significant potential to treat serious infections with significant unmet need and limited treatment options," said Jonathan Solomon, Chief Executive Officer of BiomX. "In the case of CF, BX004 has the potential to improve lung function in patients with chronic and potentially deadly pulmonary infections."

"APT's phage therapy for DFO holds the potential to prevent amputations associated with intractable infections that have penetrated into the bone in patients with diabetic foot ulcers," said Greg Merril, Founder and Board Director of APT. "With the combined intellectual and financial resources coming from this acquisition, we now have a clear line of sight towards applying this ground-breaking technology to reach multiple data readouts in CF and DFO over the next 12-24 months."

# Management and Organization

BiomX will continue to be led by its current management team, with the addition of Michael Billard from APT as General Manager, U.S. Following the transaction, the BiomX board of directors will be comprised of Dr. Russell Greig, Chair of the Board of Directors, and the following members of the board of directors - Dr. Jesse Goodman, Jonathan Leff, Dr. Alan Moses, Greg Merril, Eddie Williams and Jonathan Solomon, BiomX's Chief Executive Officer.

# About the Acquisition and the PrivatePlacement

The Acquisition is structured as a stock-for-stock transaction whereby all outstanding equity interests of APT will be exchanged in a merger for 9,164,967 shares of BiomX common stock, 40,471 shares of Series X Preferred Stock convertible into 40,471,000 shares of BiomX common stock and warrants ("Merger Warrants") exercisable for 2,166,497 shares of BiomX common stock. Following the consummation of the Acquisition, a successor-in-interest of APT will become a wholly-owned subsidiary of BiomX. The Merger Warrants will be exercisable at any time after the date of the receipt of stockholder approval at an exercise price of \$5.00 per share and will expire on January 28, 2027. The definitive merger agreement is subject to various closing conditions, including, among other conditions, receiving cash of not less than \$50 million from the private placement.

Concurrently with the entry into the definitive merger agreement with APT, BiomX entered into a definitive purchase agreement for a private placement investment with existing and new investors to raise \$50 million, in which the investors have agreed to purchase (i) an aggregate of 216,417 shares of Series X Preferred Stock and (ii) warrants ("Private Placement Warrants") to purchase up to an aggregate of 108,208,500 shares of BiomX common stock, at a combined purchase price of \$231.10 per share of Series X Preferred Stock and an accompanying Private Placement Warrant to purchase 500 shares of common stock. The Private Placement Warrants will be exercisable any time after the date of the receipt of BiomX stockholder approval, at an exercise price of \$0.2311 per share, and will

expire on the 24-month anniversary of the initial exercisability date. The closing of the private placement offering is subject to the satisfaction of customary closing conditions, including but not limited to the consummation of the Acquisition.

Subject to BiomX stockholder approval, each share of Series X Preferred Stock issued in the Acquisition and the private placement initially will be convertible into 1,000 shares of BiomX common stock, and subject to certain beneficial ownership limitations set by each holder not to exceed 19.99%. The definitive merger agreement was approved by the Board of Directors of BiomX and the Board of Directors and stockholders of APT. The closing of the Acquisition will not be subject to the approval of BiomX stockholders.

In connection with the execution of the definitive merger agreement, certain stockholders of BiomX (including its directors and officers), together holding on as converted basis over 50% of the outstanding shares of common stock of BiomX, have agreed to vote their shares in favor of the conversion of the Series X Preferred Stock.

RBC Capital Markets and Laidlaw & Company (UK) Ltd. acted as placement agents for the private placement. Haynes and Boone, LLP is serving as legal counsel to BiomX. Cooley LLP is serving as legal counsel to APT. McDermott Will & Emery LLP is serving as legal counsel to Deerfield Management. Wilmer Cutler Pickering Hale and Dorr LLP is serving as legal counsel to the placement agents.

The securities to be sold in the private placement have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or applicable state securities laws, and may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and applicable state or other jurisdictions' securities laws. BiomX has agreed to file a registration statement (the "Resale Registration Statement") with the Securities and Exchange Commission (the "SEC") registering the resale of (i) the shares of BiomX common stock issued pursuant to the Acquisition, (ii) the shares of BiomX common stock issuable upon conversion of the Series X Preferred Stock purchased in the private placement, (iii) the shares of common stock issuable upon exercise of all warrants issued in connection with the Acquisition and the private placement, (iv) the Series X Preferred Stock issued pursuant to the Acquisition and the private placement and (v) all warrants issued in connection with the Acquisition and the private placement and (v) all warrants issued in connection with the Acquisition and the private placement are contained in BiomX's Current Report on Form 8-K filed with the SEC on March 6, 2024.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of securities of BiomX in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction. Any offering of the Resale Securities under the Resale Registration Statement will only be by means of a prospectus.

Additional details are available in an updated corporate presentation that can be found online at www.biomx.com.

#### **Conference Call and Webcast Details**

BiomX will host a conference call and webcast on Mar 6, 2024 at 9:00 a.m. ET to discuss the acquisition and financing.

# **Conference Call Dial-In Information:**

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

#### 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 study 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<sup>1</sup>.

BiomX expects to initiate a randomized, double blind, placebo-controlled, multi-center Phase 2b study in CF patients with chronic *P. aeruginosa* pulmonary infections in the fourth quarter of 2024. The study 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 study 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. Study results are expected in the third quarter 2025. The U.S. Food and Drug Administration ("FDA") has granted BX004 Fast Track designation and Orphan Drug Designation.

#### About BX211

BX211 is a personalized phage treatment developed by APT 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 study 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 Adaptive Phage Therapeutics (APT)

APT is a clinical-stage company advancing therapies to treat multi-drug resistant infections. APT's approach uniquely leverages an ever-growing library of systematically discovered, selected, catalogued, and curated phages, which collectively provide broad coverage against many of the world's highest priority antibiotic-resistant bacteria. APT's technology was originally developed at the National Institutes of Health (NIH) by APT co-founder Carl R. Merril, MD CAPT USPHS (ret) and further advanced within a biodefense program of U.S. Department of Defense.

#### About BiomX

BiomX is a clinical-stage 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. For more information, please visit <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 concerning BiomX, APT, the private placement, the Acquisition and other matters. These forward-looking statements include, but are not limited to: the expected consummation of the Acquisition; future expectations, plans and prospects for BiomX following the consummation of the Acquisition; the expected consummation of the concurrent private placement; the use of proceeds from the private placement and the sufficiency of BiomX cash resources; stockholder approval of the conversion of the Series X Preferred Stock and the exercise of the warrants; the milestones of BiomX; the projected cash runway of BiomX; the status and plans for clinical trials, including the timing of data; future product development; the potential market for phage therapies; and the potential commercial opportunity of BX004 and BX211. 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 safety, tolerability and efficacy of BX004 and its potential ability to treat CF patients, as well as the potential to advance the BX004 program to a larger, pivotal Phase 2b/3 trial, if such trial is initiated, including, among other things, timing, design, enrollment, regulatory approvals and funding of such trial, 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. 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 Acquisition; the outcome of any legal proceedings that may be instituted against BiomX following the Acquisition and related transactions; the ability to obtain or maintain the listing of the common stock of BiomX on the NYSE American following the Acquisition; costs related to the Acquisition; 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; our ability to obtain, maintain and enforce intellectual property rights for our platform and development candidates; our 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 March 29, 2023, 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.

<sup>1</sup> Source: https://www.fda.gov/media/83372/download

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Source: BiomX Inc.

<sup>&</sup>lt;sup>1</sup> Predefined subgroup of patients with baseline ppFEV1<70%



Source: BiomX