May 14, 2020

# BiomX Reports First Quarter 2020 Financial Results and Provides Business Update

*Positive Phase 1 cosmetic clinical study results of BX001 in acne-prone skin reported; planned advance to Phase 2 study with readout expected in the second quarter of 2021*

*Initial BX002 Phase 1 clinical study readout in inflammatory bowel disease expected in the fourth quarter of 2020*

*Cash and equivalents of $75.3 million expected to fund current operating plan for at least 24 months*

*Company to host conference call today at 8:00 a.m. Eastern Time*

NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE: PHGE), a clinical-stage company developing natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the first quarter ended March 31, 2020.

“The highlight of the first quarter was the exciting positive topline data from our Phase 1 study of our lead candidate BX001 in subjects with acne-prone skin. Both doses of BX001 demonstrated excellent safety and tolerability, and the higher dose achieved a statistically significant reduction in target bacteria. These results represent an important step for the development of phage as a new modality – as proof of concept of phage’s potential to target bacteria in a safe and tolerable manner in a clinical setting,” said Jonathan Solomon, BiomX Chief Executive Officer. “We are very much looking forward to advancing BX001 into the Phase 2 program, as well as progressing our pipeline in inflammatory bowel disease (IBD), and primary sclerosing cholangitis (PSC).”

Following positive Phase 1 cosmetic clinical study results in acne-prone skin, the Company is advancing BX001 to a Phase 2 cosmetic clinical study, with a readout expected in the second quarter of 2021. The Phase 2 study in acne-prone skin is planned to be a 12-week randomized, double-blind, placebo-controlled trial in 100 individuals with mild-to-moderate acne. Enrolled individuals will be randomized into one of two cohorts: BX001 or placebo (vehicle). Findings from additional post hoc analyses of the Phase 1 data identified that several subject populations with a higher bacterial load at baseline, and also those with characteristics associated with a higher bacterial load at baseline, such as higher sebum levels, had an earlier and more pronounced reduction of *Cutibacterium acnes* (*C. acnes*) levels after BX001 treatment when compared to placebo (vehicle). Higher levels of bacteria result in an increased probability of interactions with phage, thereby potentially leading to a greater effect. As a result the Company plans to enrich the Phase 2 study subject population for these characteristics.

BiomX continues to drive forward its development programs in IBD and PSC, a rare liver disease. The Company expects to initiate the first-in-human Phase 1 clinical study of BX002 in IBD in 2020 and report pharmacokinetic and safety data from the study in healthy volunteers by the fourth quarter of 2020.

**COVID-19 Update**

In light of the evolving COVID-19 pandemic, BiomX has implemented recommended measures to safeguard the health and safety of its employees and the continuity of its business operations. Due to these precautions, along with challenges in clinical trial enrollment due to COVID-19, BiomX's guidance on the timing of certain clinical milestones has evolved. Updates to key upcoming milestones are detailed below.

**Recent Highlights**

- **Announced positive topline data from the Phase 1 cosmetic clinical study of BX001 in subjects with acne-prone skin**. In March 2020, BiomX announced that the study met its primary endpoint of safety and tolerability for both doses of BX001, with the high-dose BX001 treatment group achieving a statistically significant (p=0.036) reduction of *C. acnes* levels compared to placebo.

- **Announced dual listing on the Tel Aviv Stock Exchange (TASE).** In February 2020, the Company's common stock began public trading on the TASE.

**Key Upcoming Milestones**

- **Results from the Phase 2 cosmetic clinical study of BX001 expected in the second quarter of 2021.**

- **Results from the first-in-human Phase 1a study of BX002 in IBD expected in the fourth quarter of 2020.** The Phase 1a study will be conducted in healthy volunteers to provide pharmacokinetic and safety data. The Phase 1b/Phase 2a study will evaluate the eradication of the target bacteria, *Klebsiella pneumoniae*, in subjects carrying the identified bacteria with results expected in the second half of 2021.

- As the PSC program shares the same bacterial target (*Klebsiella pneumoniae*) as the IBD program, **BiomX plans to apply the Phase 1 study results in IBD to inform the PSC program, with the intention of progressing into Phase 2 development in PSC in 2022.**

- **Proof of concept in animal models in colorectal cancer by the second quarter of 2021.** BiomX's colorectal cancer program utilizes engineered phage with various payloads (such as immunostimulatory payloads) that target *Fusobacterium nucleatum* bacteria residing in the tumors of patients with colorectal cancer.

**First Quarter 2020 Financial Results**

- **Cash balance and short-term deposits as of March 31, 2020,**were $75.3 million, compared to $82.3 million as of December 31, 2019. The decrease was primarily due to net cash used in operating activities.

- **Research and development expenses** were $3.9 million in the first quarter of 2020, compared to $2.7 million in the same period of 2019. The increase was primarily due to the manufacturing of BX001 and BX002, the Company's product candidates for acne-prone skin and IBD, respectively, and the BX001 Phase 1 study.

- **General and administrative expenses** were $2.1 million in the first quarter of 2020, compared to $1.0 million in the same period in 2019. The increase was mostly due to expenses associated with public company infrastructure.

- **Net loss** was $5.9 million in the first quarter of 2020, compared to $3.2 million in the same period of 2019.

- **Net cash used in operating activities** of $6.7 million in the first quarter of 2020, compared to $3.0 million in the same period of 2019.

**Financial Expectations**

- The Company believes that its existing cash, cash equivalent and short-term deposits will be sufficient to fund its current operating plan for at least 24 months.

**Conference Call Details**

BiomX management will host a conference call and webcast today at 8:00 a.m. ET to report financial results for the first quarter of 2020 and provide business updates. To participate in the conference call, please register at http://dpregister.com/10144165 ahead of the call to receive dial-in information or please dial 1-866-777-2509 for participants based in the United States, 1-412-317-5413 for participants based outside the United States, or 1-80-9212373 for participants based in Israel and ask to be joined into the BiomX first quarter earnings conference call. A live webcast of the call will be available on the Investors section of the BiomX website and a replay will be available after its completion.

**About the Phase 1 Cosmetic Clinical Study of BX001 in Acne-Prone Skin**

The Phase 1 cosmetic clinical study was a four-week randomized, double-blind, dose-finding, placebo-controlled single center trial which enrolled 75 individuals with mild-to-moderate acne. Enrolled individuals were randomized into one of three cohorts: a high dose cohort, a low dose cohort, and a placebo cohort (vehicle).

**About Phage**
Bacteriophage, or phage, are viruses that target bacteria and are considered inert to mammalian cells. Phage are designed to target and kill specific bacterial species or strains without disrupting other bacteria or the healthy microbiota. All of BiomX's phage-based product candidates derive from its proprietary platform, which is first used to discover and validate the association and biologic rationale of specific bacterial strains with human diseases or conditions, and is then used to develop rationally-designed phage combinations ("cocktails") of naturally occurring or synthetic phage to target pathogenic bacteria. The phage cocktails contain multiple phage with complementary functions optimized through in vitro and in vivo testing.

**About BiomX**
BiomX is a clinical-stage biotechnology company developing both natural and engineered

phage cocktails designed to target and destroy bacteria that affect the appearance of skin, as well as harmful bacteria in chronic diseases, such as inflammatory bowel disease (IBD), primary sclerosing cholangitis (PSC), and colorectal cancer (CRC). BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.
www.biomx.com

**Safe Harbor Language**
This press release contains certain “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. 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 additional disclosures we make in the Company’s filings with the Securities and Exchange Commission (the “SEC”), which are available on the SEC’s website at www.sec.gov.

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Source: BiomX Inc.