BiomX Reports Second Quarter 2020 Financial Results and Provides Business Update

– Expect to initiate Phase 1a clinical study of BX002 for the treatment of IBD in the third quarter of 2020; pharmacokinetics results expected by the end of 2020

– On track for Phase 2 cosmetic clinical study of BX001 in acne first quarter of 2021

– Cash and equivalents of $70.6 million expected to fund current operating plan through mid-2022

– 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 second quarter ended June 30, 2020.

“Following proof of concept clinical results for our phage therapy cocktail BX001 in acne-prone skin earlier this year, we continue to advance the development of multiple phage therapy candidates that have the potential to improve treatment in diverse disease areas,” commented Jonathan Solomon, Chief Executive Officer of BiomX. “These candidates are designed with the ability to selectively reduce pathogenic bacterial strains without disrupting beneficial bacteria. Our BX002 program for the treatment of inflammatory bowel disease (IBD) is on track to begin clinical development in the third quarter, with the initial goal of demonstrating an ability to deliver viable phage to the lower gastrointestinal tract. We expect to report pharmacokinetics and safety data from the study by the end of 2020. This is an important step in our clinical development plans for both IBD and primary sclerosing cholangitis (PSC). The Phase 1a results are expected to inform the design of a Phase 1b/2a study aimed at evaluating the efficacy of BX002 in reduction of the target bacteria.”

Recent Highlights and Key Upcoming Milestones

BX002 for the Treatment of Inflammatory Bowel Disease

- BiomX has completed GMP manufacturing of phage in anticipation of a planned Phase 1a and the facility can now support multiple clinical trials simultaneously.
- The first-in-human Phase 1a study of BX002 is expected to begin in the third quarter of 2020, with results expected by the end of 2020. The study is designed to provide pharmacokinetic measurements and safety data, including an assessment of delivery of viable phage to the gastrointestinal system as a key exploratory endpoint.
- A Phase 1b/2a study aimed at evaluating the efficacy of BX002 in reduction of the
target bacteria *Klebsiella pneumoniae* is expected to begin in 2021.

**BX001 for the Cosmetic Market for the Appearance of Acne-Prone Skin**

- Following positive results from its Phase 1 cosmetic clinical study, BiomX is on track to initiate a Phase 2 cosmetic clinical study in the first quarter of 2021 with results expected in the second quarter of 2021.

**BX003 for the Treatment of Primary Sclerosing Cholangitis**

- The Company’s program in the rare liver disease primary sclerosing cholangitis (PSC) 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 2022.

**Phage Therapy for Tumor-Targeted Delivery in Cancer**

- BiomX is exploring phage mediated delivery of therapeutic payloads to *Fusobacterium nucleatum* bacteria residing in the tumors of patients with colorectal cancer. The results of a proof of concept in animal models are expected in the second quarter of 2021.

**Second Quarter 2020 Financial Results**

- **Cash balance and short-term deposits as of June 30, 2020,** were $70.6 million, compared to $82.4 million as of December 31, 2019. The decrease was primarily due to net cash used in operating activities.
- **Research and development expenses** were $4.1 million in the second quarter of 2020, compared to $2.9 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/PSC, respectively.
- **General and administrative expenses** were $2.3 million in the second quarter of 2020, compared to $1.2 million in the same period in 2019. The increase was primarily due to expenses associated with operating as a public company.
- **Net loss** was $6.2 million in the second quarter of 2020, compared to $3.8 million in the same period of 2019.
- **Net cash used in operating activities** was $11.4 million for the six months ended June 30, 2020, compared to $5.9 million in the same period of 2019.

**Financial Expectations**

- Existing cash, cash equivalents and short-term deposits are expected to be sufficient to fund the Company’s current operating plan through mid-2022.

**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 second quarter of 2020 and provide business updates. To participate in the conference call, 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 in the Investors section of the company’s website at [www.biomx.com](http://www.biomx.com).
About Phage

Bacteriophage, or phage, are viruses that target bacteria and are considered inert to mammalian cells. Specific phage can 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.

Safe Harbor Language

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 clinical and pre-clinical development program, including timing and milestones thereof, the design and potential of its product candidates, the potential effect of COVID-19 on BiomX’s business, sufficiency of financial resources and how long BiomX’s cash and cash equivalents are expected to fund its operations 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 most recent Annual Report on Form 10-K and additional disclosures BiomX makes in its filings with the Securities and Exchange Commission (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 BiomX expressly disclaims any obligation or undertaking to update forward-looking statements.

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Source: BiomX Inc.