

# BiomX Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

- Initiated Phase 2 cosmetic clinical study for BX001 in subjects with acne-prone skin; results expected from 8-week treatment period in Q3 2021
  - Results from Phase 2 proof-of-concept clinical study of newly selected phage cocktail candidate, BX004, in cystic fibrosis expected to readout in Q4 2021
- Phase 2 proof-of-concept clinical study of newly selected phage cocktail candidate, BX005, in atopic dermatitis expected to initiate in second half of 2021
  - Company will host a conference call and webcast today at 8:00 am ET

NESS ZIONA, Israel--(BUSINESS WIRE)--

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, today reported financial results and provided a business update for the fourth quarter and full year ended December 31, 2020.

"2020 was a tremendous year of growth for BiomX, as we expanded our pipeline with programs in cystic fibrosis and atopic dermatitis, both designed to address unmet medical needs," said Jonathan Solomon, Chief Executive Officer of BiomX. "Fueled by the rapid development capabilities of our novel BOLT platform, we are excited to announce today that we have selected two new phage cocktail candidates, BX004 and BX005, for cystic fibrosis and atopic dermatitis, respectively."

Mr. Solomon added, "2021 is poised to be a year of multiple potential value inflection points for BiomX, due to anticipated efficacy data readouts from two Phase 2 clinical studies, BX001 in subjects with mild-to-moderate acne and BX004 in subjects with cystic fibrosis. Due to the historic safety of phage therapies and the cutting-edge capabilities of our BOLT platform, we are accelerating toward additional efficacy readouts by mid-2022 for our inflammatory bowel disease and atopic dermatitis programs, which are large market opportunities. We believe phage could play a substantial role in the growing field of microbiome therapies."

#### RECENT HIGHLIGHTS AND KEY UPCOMING MILESTONES

## **Acne-Prone Skin**

 Earlier this month, BiomX announced the dosing of the first subject in a Phase 2 cosmetic clinical study of BX001 in subjects with mild-to-moderate acne over the course of 12 weeks, a longer duration than the Phase 1 study. Results from 8-week and 12-week timepoints are expected in the third and fourth quarter of 2021, respectively.

• In March 2020, BiomX reported positive data from the Phase 1 cosmetic clinical study of BX001 in subjects with acne-prone skin, where BX001 was shown to be safe and tolerable, as well as demonstrated a statistically significant reduction of *Cutibacterium acnes* levels with the high dose compared to placebo.

## Inflammatory Bowel Disease ("IBD") and Primary Sclerosing Cholangitis ("PSC")

- In February 2021, BiomX announced positive results from a first-in-human Phase 1a pharmacokinetic study of BX002 in the IBD/PSC program, the first ever clinical study detailing pharmacokinetics of an oral phage therapy under a U.S. Food and Drug Administration ("FDA") IND approved protocol. BX002 demonstrated safety and tolerability with successful delivery of a high concentration of viable phage to the lower gastrointestinal tract, specifically at levels approximately 1,000 times the bacterial burden of the target bacteria, Klebsiella pneumoniae, in IBD and PSC patients as measured in stool.
- Based on the Phase 1a study results, BiomX plans to initiate a Phase 1b/2a study with results expected by mid-2022. The Phase 1b/2a study will evaluate the efficacy of BX003 in reducing the intestinal bacterial burden of *Klebsiella pneumoniae* in target bacteria carriers. In November 2020, the Company consolidated its IBD and PSC programs into one product candidate, BX003, with a broad host range for both indications.

# **Cystic Fibrosis ("CF")**

- The Company today announced the selection of the phage cocktail candidate, BX004, for subjects with CF, specifically for the treatment of chronic lung infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with this and other underlying conditions. In preclinical *in vitro* studies, BX004 was shown to be active against antibiotic resistant strains of *Pseudomonas aeruginosa* and demonstrated the ability to penetrate biofilm, an assemblage of surface-associated microbial cells enclosed in an extracellular polymeric substance and one of the leading causes for antibiotic resistance.
- Phase 2 results of a proof-of-concept clinical study evaluating the safety and efficacy of BX004 in CF patients are expected in the fourth quarter of 2021.

## **Atopic Dermatitis**

• The Company today announced the selection of the phage cocktail candidate, BX005, for subjects with atopic dermatitis, specifically to target Staphylococcus aureus, a bacterium linked to the development and exacerbation of inflammation in atopic dermatitis. In preclinical in vitro studies, BX005 was shown to be active against over 90% of strains from a panel of Staphylococcus aureus, including antibiotic resistant strains, isolated from the skin of subjects in the U.S. and Europe.

• BiomX expects to initiate a Phase 2 proof-of-concept clinical study evaluating the safety and efficacy of BX005 in atopic dermatitis patients in the second half of 2021, with results expected in the first half of 2022.

#### **Colorectal Cancer**

- BiomX is exploring phage-mediated delivery of therapeutic payloads for the treatment of colorectal cancer, such as immune-stimulating proteins, GM-CSF and IL-15, to target Fusobacterium nucleatum bacteria, which is present within colorectal tumors. In December 2020, BiomX presented preclinical results confirming the presence of Fusobacterium nucleatum in 80% of tumor samples collected from patients with colorectal cancer, at the European Society of Medical Oncology ("ESMO") Immuno-Oncology Virtual Congress. The Company has also successfully engineered an IL-15 gene payload into Fusobacterium nucleatum phage.
- BiomX previously disclosed data from preclinical models demonstrating that intravenously administered phage has the ability to target bacteria inside colorectal cancer tumors.
- Preclinical results from animal studies evaluating use of phage therapy in combination with checkpoint inhibitors are expected in the second and third quarters of 2021.

## **Corporate and Business Highlights**

- In September 2020, BiomX entered into a collaboration with Boehringer Ingelheim to utilize BiomX's XMarker, a microbiome-based discovery platform to potentially identify biomarkers associated with patient phenotypes in IBD.
- In October 2020, BiomX announced the appointment of Paul Sekhri and Alan Moses,
  M.D., to its Board of Directors.

#### Fourth Quarter and Full Year 2020 Financial Results

- Cash balance and short-term deposits as of December 31, 2020, were \$57.1 million, compared to \$82.4 million as of December 31, 2019. The decrease was primarily due to net cash used in operating activities. Existing cash, cash equivalents and short-term deposits are expected to be sufficient to fund the Company's current operating plan and capital expenditure requirements through mid-2022.
- Research and development (R&D) expenses, netwere \$6.5 million for the three months ended December 31, 2020, compared to \$5 million for the same period in 2019. R&D expenses, net were \$21 million for the year ended December 31, 2020, compared to \$13.5 million for the prior year. The full year increase was primarily due to the growth in number of employees, resulting in additional stock-based compensation, salaries and related expenses, and due to manufacturing of candidate products for clinical trials in acne-prone skin and IBD/PSC.
- **General and administrative (G&A) expenses** were \$2.6 million for the three months ended December 31, 2020, compared to \$4.7 million for the same period in 2019. G&A expenses were \$9.3 million for the year ended December 31, 2020, compared to \$8.7 million for the prior year. In the fourth quarter of 2019 the expenses included merger-

related costs. The full year increase was primarily due to expenses associated with operating as a public company, such as directors' and officers' insurance, filing and legal and accounting expenses.

- **Net loss** for the fourth quarter of 2020 was \$9.1 million, compared to \$9.3 million for the same period in 2019. For the full year 2020 net loss was \$30.1 million, compared to \$20.6 million for the prior year.
- **Net cash used in operating activities** for the full year 2020 was \$24.4 million, compared to \$17.6 million in 2019.

#### **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 corporate updates for the fourth quarter and year ended December 31, 2020. 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 <a href="https://www.biomx.com">www.biomx.com</a>

## **About Phage Therapy**

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. BiomX's phage-based product candidates derive from its proprietary BOLT ("BacteriOphage Lead to Treatment") R&D platform that enables the company to rapidly develop, manufacture and formulate 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 microbiome company developing both natural and engineered phage cocktails designed to target and destroy bacteria that affect the appearance of skin, as well as target bacteria in the treatment of chronic diseases, such as inflammatory bowel disease, primary sclerosing cholangitis, cystic fibrosis, atopic dermatitis and colorectal cancer. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at <a href="https://www.biomx.com">www.biomx.com</a>, 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 potential markets opportunities, the capabilities of the BOLT platform, the design, aim, expected timing, and interim and final

results of its preclinical and clinical trials and studies, the sufficiency of its existing cash, cash equivalents and short-term deposits, 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 forwardlooking 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 forwardlooking statements and should review the risks and uncertainties described under the caption "Risk Factors" in BiomX's Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on December 4, 2020 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 except as provided by law BiomX expressly disclaims any obligation or undertaking to update forward-looking statements.

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