BiomX Reports Full Year 2019 Financial Results and Provides Business Update

- On track to announce BX001 Phase 1 acne data at the end of the first quarter 2020 -

NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE: PHGE), a clinical-stage biotechnology company developing both natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the full year ended December 31, 2019.

“2019 was a landmark year for BiomX as we advanced our lead program in acne-prone individuals into the clinic and, through our merger, listed publicly on the NYSE American stock exchange,” said Jonathan Solomon, BiomX Chief Executive Officer. “Phage can target and kill specific bacteria. This property, combined with an excellent safety record, creates the potential for it to become a disruptive therapeutic modality for the treatment of chronic diseases in which bacteria play a causative role. With our phage cocktail customization capabilities, cutting-edge synthetic biology, computational biology tools, phage manufacturing facilities and a strong financial position, we believe we are well positioned to leverage phages’ unique potential and develop important and novel therapeutics. We continue to be on track to announce data from our Phase 1 study of our lead candidate BX001 in subjects with acne prone skin at the end of the first quarter of 2020 and Phase 1 data for our inflammatory bowel disease program in the fourth quarter of 2020.”

COVID-19 Update

In light of the evolving COVID-19 pandemic, BiomX has implemented all recommended measures to safeguard the health and safety of its employees and the continuity of its business operations. The Company’s research and development programs currently remain on schedule. In addition BiomX enjoys a strong cash position with over $82 million in cash, cash equivalents and short-term deposits as of the end of 2019.

Recent Highlights

Development Programs

- Completed enrollment of a Phase 1 cosmetic clinical study in subjects with acne-prone skin. BiomX completed enrollment in a first-in-human cosmetic clinical study of BX001 in 75 subjects with mild to moderate acne. BX001 is a topically administered gel comprised of a cocktail of naturally occurring phage designed to address the appearance of acne by targeting Cutibacterium acnes (or C. acnes, formerly taxonomically classified as P. acnes), a bacterium implicated in the pathophysiology of acne vulgaris.

- Pre-IND meeting held with FDA and manufacturing initiated for BX002 for the
treatment of Inflammatory Bowel Disease (IBD). BX002 is a phage cocktail targeting strains of *Klebsiella pneumoniae* that have been shown in animal models to be pro-inflammatory and pathogenic and may have a role in the onset and aggravation of the disease in humans. BiomX has advanced towards the clinic with a pre-Investigational New Drug (IND) regulatory meeting and initiated manufacturing for clinical trials in this indication.

- **Presented preclinical results from program targeting Primary Sclerosing Cholangitis (PSC) at AASLD conference.** BiomX presented *in vivo* data on a phage cocktail that substantially reduced bacterial burden of pathogenic *Klebsiella pneumoniae* strains which are thought to be disease modifying in PSC, a rare progressive liver disorder with no FDA-approved treatment.

- **Presented preclinical results from colorectal cancer program at AACR Microbiome, Viruses, and Cancer Conference.** BiomX presented preclinical *in vivo* data on phage that target *Fusobacterium nucleatum*, a bacterium present in the microenvironment of colorectal cancer tumors and thought to protect tumors from the host’s immune system. BiomX also successfully applied synthetic engineering to convert phage from temperate (lysogenic) to lytic, the state in which phage kill bacteria.

- **Completed construction of in-house phage manufacturing facility.** The new facility, located at the Company’s headquarters, supports clinical manufacturing of candidate phage products and in the future could be expanded to support commercial manufacturing needs.

**Corporate**

- **Successfully completed merger resulting with a NYSE American stock exchange public listing and significant capital.** In October 2019, BiomX announced closing of the merger with Chardan Healthcare Acquisition Corp. with $60.1 million raised.

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

- **Announced additions to Board of Directors and Senior Management.** BiomX announced the addition of Russell G. Greig, Ph.D., as Chairman and Lynne Sullivan as Director to the BiomX Board and Chair of the Audit Committee. On October 2019, Merav Bassan, Ph.D., was appointed Chief Development Officer.

**Key Upcoming Milestones**

- **Data from the phase 1 cosmetic clinical study of BX001 in subjects with acne-prone skin to be announced at the end of the first quarter of 2020.** The primary endpoints of the randomized, double-blind, dose-ranging, vehicle-controlled study are safety and tolerability. Exploratory endpoints include proof of principle by measurement of the effect of BX001 on *C. acnes* levels.

- **Data from the phase 1 study of BX002 in inflammatory bowel disease to be announced in the fourth quarter of 2020.**
Engineering *F. nucleatum* phage with various payloads (such as immunostimulatory payloads) and initiating proof of concept in animal models by the fourth quarter of 2020.

Full Year 2019 Financial Results

- **Cash balance and short-term deposits as of December 31, 2019** were $82.3 million, compared to $40 million as of December 31, 2018. The increase was mainly due to funds raised through completion of the merger with Chardan Healthcare Acquisition Corp.

- **Research and development expenses** of $13.5 million in 2019, compared to $9.1 million in 2018. The increase was attributed mostly to the manufacturing of BX001 and BX002, the Company’s product candidates for acne-prone skin, and IBD, respectively, and due to initiation of the BX001 clinical study.

- **General and administrative expenses** of $8.7 million in 2019, compared to $3.4 million in 2018, mainly due to merger-related expenses and construction of the Company’s in-house manufacturing facility.

- **Net loss** of $20.6 million in 2019, compared to $12.7 million in 2018.

- **Net cash used in operating activities** of $17.6 million in 2019, compared to $11.3 million in 2018.

1. Atarashi et al. (2017), *Science*
2. Nakamoto et al. (2019), *Nature Microbiology*
3. Bullman et al. (2017), *Science*

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. All of BiomX’s phage-based product candidates derive from its proprietary platform, which is first used to discover and validate the association 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](http://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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