

November 12, 2020



# **BiomX Reports Third Quarter 2020 Financial Results and Announces Expanded Portfolio of Phage Therapy Candidates**

*Company unveils BOLT (Bacteriophage Lead to Treatment) platform designed for more rapid and efficient development of phage therapy*

*BOLT enables the Company to expand portfolio with two additional phage therapy programs in cystic fibrosis and atopic dermatitis and allows consolidation of two programs into one product candidate, BX003, for the treatment of both inflammatory bowel disease (IBD) and primary sclerosing cholangitis (PSC)*

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

NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE American: PHGE), a clinical stage company developing natural and engineered phage therapies targeting specific pathogenic bacteria, today reported financial results and a business update for the third quarter ended September 30, 2020.

“BiomX continues to lead in the field of phage therapy by implementing proprietary processes for accelerated development,” commented Jonathan Solomon, Chief Executive Officer of BiomX. “Our novel BOLT platform, which is the result of an accumulated five years of technological development, significantly reduces the time required to reach clinical proof-of-concept. The improved efficiency of this platform allows us to expand our portfolio with two significant new programs without affecting our projected cash runway.”

Continued Mr. Solomon, “This expansion includes near term opportunities with phage therapy candidates. We expect clinical proof of concept results in patients for cystic fibrosis and atopic dermatitis by the end of 2021 and mid-2022, respectively. Improvements in R&D also allow for the consolidation of our inflammatory bowel disease (IBD) and primary sclerosing cholangitis (PSC) programs. We now have one improved, broad host range product candidate, BX003, targeting *Klebsiella pneumoniae*, a potential pathogen implicated in both diseases to be developed for both indications. The consolidation of these programs results in an updated timeline for Phase 1b/2a results with BX003 expected in mid-2022. In addition, we expect data from a planned Phase 2 cosmetic clinical study in acne-prone skin in the second quarter of 2021.”

## **About the BOLT Platform**

The newly unveiled BOLT (“Bacteriophage Lead to Treatment”) R&D platform enables BiomX to rapidly develop, manufacture and formulate a phage treatment targeting a given

pathogenic bacteria. The platform allows BiomX to conduct an initial clinical proof of concept study in patients (Phase 2 results) within approximately 12-18 months of project initiation<sup>1</sup>. The ability to move quickly into clinical development is also driven by the strong safety profile of naturally-occurring phage, as corroborated by regulatory guidance provided to BiomX by the FDA as relating to its IBD program, allowing the Company to bypass safety studies and studies in healthy volunteers and to proceed directly to patient studies.

## Recent Highlights and Key Upcoming Milestones

### Acne-Prone Skin

- The Company expects to initiate a Phase 2 cosmetic clinical study of phage therapy BX001 in the first quarter of 2021, with results expected in the second quarter of 2021.

### Cystic Fibrosis

- A new program for development of a phage therapy targeting chronic respiratory infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with cystic fibrosis. Phase 2 results of a proof of concept clinical study evaluating safety and efficacy in patients are expected in the fourth quarter of 2021.

### Atopic Dermatitis

- A new program for development of a topically administered phage therapy targeting *Staphylococcus aureus*, a bacterium linked to the development and exacerbation of inflammation in atopic dermatitis. Phase 2 results of a proof of concept clinical study evaluating safety and efficacy in patients are expected in the first half of 2022.

### IBD and PSC

- Results of a Phase 1a study are expected in the first quarter of 2021. The study is designed to provide safety and pharmacokinetic data, including an assessment of delivery of viable phage to the gastrointestinal system as a key exploratory endpoint.
- Results of the Phase 1b/2a study aimed at evaluating the efficacy of BX003, improved broad host range phage therapy, in reduction of the target bacteria *Klebsiella pneumoniae* are expected by mid-2022.

### 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. Preclinical results from animal studies evaluating use of phage therapy in combination with checkpoint inhibitors are expected in the second quarter of 2021.

### Biomarker Discovery Collaboration with Boehringer Ingelheim

- In September 2020, BiomX entered into a collaboration with Boehringer Ingelheim to utilize the BiomX XMarker microbiome-based biomarker discovery platform to potentially identify biomarkers associated with patient phenotypes in IBD.

## Third Quarter 2020 Financial Results

- **Cash balance and short-term deposits as of September 30, 2020**, were \$64.5 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 \$6.4 million in the third quarter of 2020, compared to \$2.9 million in the same period of 2019. The increase was primarily due to growth in the number of employees which resulted in an increase of salaries and related expenses and due to an increase in depreciation and amortization expenses.
- **General and administrative expenses** were \$2.4 million in the third quarter of 2020, compared to \$1.8 million in the same period in 2019. The 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** was \$8.8 million in the third quarter of 2020, compared to \$4.3 million in the same period of 2019.
- **Net cash used in operating activities** was \$17.3 million for the nine months ended September 30, 2020, compared to \$10.5 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 third 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 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 target bacteria in the treatment of chronic diseases, such as inflammatory bowel disease, primary sclerosing cholangitis, cystic fibrosis and colorectal cancer. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at [www.biomx.com](http://www.biomx.com), the content of which does not form a part of this press release.

## 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 the potential opportunities for and benefits of the BOLT platform, the expected timing of initiation and receipt of results from its various pre-clinical and clinical studies as well as the acceptance of regulatory agencies of the design thereof, its collaboration with Boehringer Ingelheim and the potential thereof and the sufficiency of its funding through mid-2022, 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 Quarterly Report on Form 10-Q 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](http://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> In certain indications the length of clinical proof of concept may be longer depending on indication, identity of target bacteria, recruitment rate, cohort size and other factors.

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