# 2021 ANNUAL REPORT

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 10-K

**☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended **December 31, 2021**

or

**☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: **0001-38762**

**BIOMX INC.**
(Exact name of registrant as specified in its charter)

| **Delaware** | **82-3364020** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **22 Einstein St., Floor 5, Ness Ziona, Israel** | **7414003** |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: **+972 723942377**

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Units, each consisting of one share of common stock, $0.0001 par value, and one Warrant entitling the holder to receive one half share of common stock | PHGE.U | NYSE American |
| Common stock, $0.0001 par value | PHGE | NYSE American |
| Warrants, each exercisable for one-half of a share of common stock, $0.0001 par value, at an exercise price of $11.50 per share | PHGE.WS | NYSE American |

Securities registered pursuant to Section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging Growth Company | ☒ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On June 30, 2021, the last day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the Registrant's shares of Common Stock held by non-affiliates of the Registrant was $119,922,575 based on the closing sale price of the Registrant's shares of Common Stock on June 30, 2021 (the last trading day of the fiscal quarter) of $5.46 per share.

The number of shares outstanding of the Registrant's shares of Common Stock as of March 25, 2022 was 29,779,249.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, relating to the registrant's 2022 Annual Meeting of Stockholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K. The definitive proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2021.

**BIOMX INC.**
**Annual Report on Form 10-K for the Year Ended December 31, 2021**

*References in this Annual Report on Form 10-K (this "Annual Report") to the Company, BiomX, we, us or our, mean BiomX Inc. and its consolidated subsidiaries unless otherwise expressly stated or the context indicates otherwise. References in this Annual Report to BiomX Ltd. mean BiomX Ltd., our wholly owned Israeli subsidiary. As further described elsewhere in this Annual Report, on October 28, 2019, Chardan Healthcare Acquisition Corp., a special purpose acquisition company, combined with BiomX Ltd. in the Business Combination (as defined below) and changed its name to BiomX Inc.*

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended or the Exchange Act. The statements contained in this report that are not purely historical are forward-looking statements. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "will" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Examples of forward-looking statements in this report include, but are not limited to, statements regarding our disclosure concerning our operations, cash flows, financial position and also regarding our preclinical and clinical development plans, the safety, tolerability and efficacy of our phage therapy and the conducting, design, aims and timing of its preclinical and clinical studies and announcing results thereof.

Forward-looking statements appear in a number of places in this report including, without limitation, in the sections entitled "Management's Discussion and Analysis of Financial Conditions and Results of Operations," and "Overview." The risks and uncertainties include, but are not limited to:

- the ability to generate revenues, and raise sufficient financing to meet working capital requirements;
- the unpredictable timing and cost associated with our approach to developing product candidates using phage technology;
- the continued impact of the COVID-19 pandemic on general economic conditions, our operations, the continuity of our business, including our preclinical and clinical trials, and our ability to raise additional capital;
- political and economic instability, including, without limitation, due to natural disasters or other catastrophic events, such as the Russian invasion of Ukraine and world sanctions on Russia, Belarus, and related parties, terrorist attacks, hurricanes, fire, floods, pollution and earthquakes;
- obtaining U.S. Food and Drug Administration, or FDA, acceptance of any non-U.S. clinical trials of product candidates;
- the ability to pursue and effectively develop new product opportunities and acquisitions and to obtain value from such product opportunities and acquisitions;
- penalties and market withdrawal associated with any unanticipated problems with product candidates and failure to comply with labeling and other restrictions;
- expenses associated with compliance with ongoing regulatory obligations and successful continuing regulatory review;
- market acceptance of our product candidates and ability to identify or discover additional product candidates;
- our ability to obtain high titers for specific phage cocktails necessary for preclinical and clinical testing;
- the availability of specialty raw materials and global supply chain challenges;
- the ability of our product candidates to demonstrate requisite safety and efficacy for drug products, or safety, purity and potency for biologics without causing adverse effects;
- the success of expected future advanced clinical trials of our product candidates;
- our ability to obtain required regulatory approvals;
- our ability to enroll patients in clinical trials and achieve anticipated development milestones when expected;
- delays in developing manufacturing processes for our product candidates;
- competition from similar technologies, products that are more effective, safer or more affordable than our product candidates or products that obtain marketing approval before our product candidates;

- the impact of unfavorable pricing regulations or third-party coverage and reimbursement policies on our ability to sell product candidates or therapies profitably;
- protection of our intellectual property rights and compliance with the terms and conditions of current and future licenses with third parties;
- infringement on the intellectual property rights of third parties and claims for remuneration or royalties for assigned service invention rights;
- our ability to acquire, in-license or use proprietary rights held by third parties necessary to our product candidates or future development candidates;
- ethical, legal and social concerns about synthetic biology and genetic engineering that may adversely affect market acceptance of our product candidates;
- reliance on third-party collaborators;
- our ability to manage the growth of the business;
- our ability to attract and retain key employees or to enforce the terms of noncompetition agreements with employees;
- the failure to comply with applicable laws and regulations;
- potential security breaches, including cybersecurity incidents;
- receipt of the second and/or third tranches under the Term Loan Facility, as such term is defined below, or the second tranche under our agreement with the Cystic Fibrosis Foundation;
- political, economic and military instability in the State of Israel; and
- other factors discussed in the section of this report entitled "Risk Factors" beginning on page 33.

Forward-looking statements are subject to known and unknown risks and uncertainties and are based on our management's potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. While these statements are based upon information available to us as of the filing date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in "Risk Factors" in this Annual Report. Except as may be required by applicable law, we undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this report or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or the SEC, after the date of this report.

## RISK FACTORS SUMMARY

The summary below provides an overview of many of the risks the Company faces, and a more detailed discussion of risks can be found in Item 1A. "Risk Factors" below. You should carefully consider these risks and uncertainties when investing in our securities. The principal risks and uncertainties affecting our business include, but are not limited to, the following:

- We are a clinical-stage company with limited operating history, we have never generated any revenue from product sales and may never be profitable. We anticipate that we will continue to incur significant losses for the foreseeable future.
- We will need to raise additional capital in the future to support our operations which may not be available at terms that are favorable to us and might cause significant dilution to our stockholders or increase our debt towards third parties.
- We are seeking to develop product candidates using phage technology, an approach for which it is difficult to predict the potential success and time and cost of development. To our knowledge, no bacteriophage has thus far been approved as a drug in the United States or in the European Union.
- Our product candidates must undergo clinical testing which may fail to demonstrate the requisite safety and efficacy for drug products, or safety, purity, and potency for biologics, and any of our product candidates could cause adverse effects, which would substantially delay or prevent regulatory approval and/or commercialization.
- The COVID-19 pandemic has affected and may continue to adversely affect our business, including our clinical trials.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates for therapeutic indications, we will not be able to commercialize, or will be delayed in commercializing them.

- Regulatory requirements for development of our product candidates are uncertain and evolving. Changes in these laws or the current interpretation or application of these laws would have a significant adverse impact on our ability to develop and commercialize our product candidates. Our success is also largely dependent on a broad degree of market acceptance of our product candidates and, in the case of drug products, physician adoption and use, which are necessary for commercial success.

- Initiating, managing and completing clinical trials entails many risks, including in enrolling patients, non-performance of third parties we rely on to manage and perform clinical trials, delays and adverse effects. Even if successfully completed, results from clinical studies may not be replicated in subsequent clinical trials.

- If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.

- Legal requirements as well as ethical and social concerns about synthetic biology and genetic engineering could limit or prevent the use of our technologies and limit our revenues.

- There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities to us.

- Failure to comply with health and data protection laws and regulations could lead to claims, government enforcement actions, regulatory actions, private litigation and/or adverse publicity. In addition, our business and operations might be adversely affected by security breaches, including any cybersecurity incidents.

- Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and other consequences.

- Even if we receive regulatory approval of any product candidates for therapeutic indications, we will be subject to ongoing regulatory compliance obligations and continued regulatory review as well as unfavorable health care legislative and regulatory reform measures. Additionally, any of our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

- We are highly dependent on intellectual property licensed from third parties, collaborations with third parties in research and development and manufacturing of our clinical supply of product candidates. Termination or limitation of any of these licenses as well as third party collaborations could result in the loss of significant rights and materially harm our business.

- We are dependent on patents and proprietary technology such as trade secrets and other forms of non-patent intellectual property protection. If we fail to adequately protect this intellectual property our ability to commercialize products could suffer. If we infringe the rights of third parties, we could be prevented from selling products, forced to pay damages and/or royalties, and forced to defend against litigation which might be very expensive to us.

- We rely on our BacteriOphage Lead to Treatment, or BOLT, proprietary product platform to develop our phage therapies. Our competitive position could be materially harmed if our competitors develop similar platforms and develop rival product candidates.

- Because our headquarters and principal facilities are located in the State of Israel, we are exposed to potential political, economic and military instability in Israel that might adversely affect us.

- We have received, and may continue to receive, Israeli and other governmental grants to assist in the funding of our research and development activities. If we lose such funding we may encounter difficulties in the funding of future research and development. In addition, such Israeli government grants restrict our ability to manufacture products and transfer technology outside of Israel and require us to satisfy specified conditions. If we fail to satisfy such conditions, we may be required to refund grants, together with interest and penalties.

- We incur significant costs operating as a public company, including significant management attention to maintaining and improving our internal control over financial reporting and the requirements of being a public company which may, among other things, strain our resources and divert management's attention.

- Exchange rate fluctuations between the U.S. Dollar, the New Israeli Shekel, the Euro and other foreign currencies, may negatively affect our future revenues and expenses.

## PART I

### ITEM 1. BUSINESS

**Overview**

We are a clinical stage microbiome product discovery company developing products using both natural and engineered phage technologies designed to target and kill specific harmful bacteria associated with chronic diseases, such as cystic fibrosis, or CF, atopic dermatitis, or AD, inflammatory bowel disease, or IBD, primary sclerosing cholangitis, or PSC and colorectal cancer, or CRC. Bacteriophage or phage are bacterial, species-specific, strain-limited viruses that infect, amplify and kill the target bacteria and are considered inert to mammalian cells. By utilizing proprietary combinations of naturally occurring phage and by creating novel phage using synthetic biology, we develop phage-based therapies intended to address both large-market and orphan diseases.

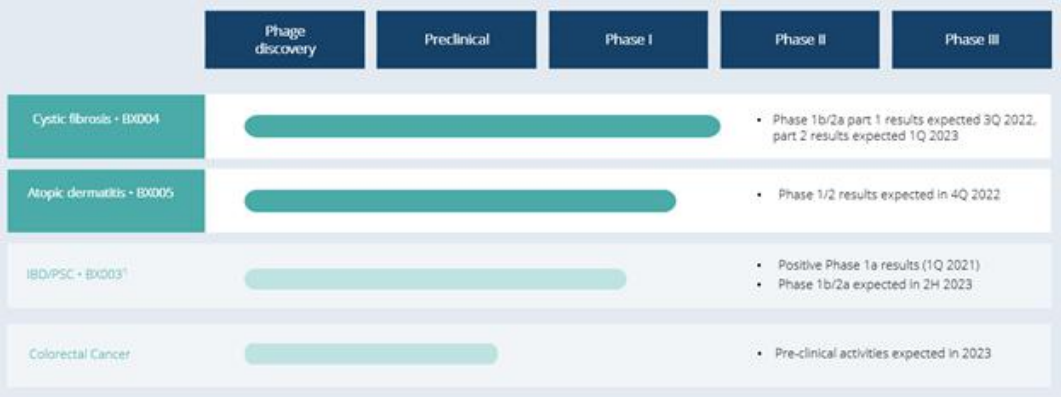
The microbiome refers to the collection of microorganisms, including phage, that reside on the skin, line the gastrointestinal tract and reside elsewhere in the body. The vast majority of these microorganisms are not pathogenic and instead exist in a symbiotic state with the human host, enabling the body to function normally by protecting against proliferation of pathogenic strains, educating the immune system and assisting in digestion. Imbalances in the composition of the microbiome have been found in multiple diseases.

Our approach in our therapeutic programs is based on targeting those specific strains of pathogenic bacteria in the microbiome that are strongly associated with diseases while leaving the rest of the microbiome intact. Our goal is to restore the natural, healthy balance of the microbiome with rationally designed phage cocktails. Using our proprietary methods, we can generate and screen large libraries of phage, prioritizing potential candidates based on selectivity and potency as well as a number of other parameters, that are important for drug development such as safety, stability and manufacturability.

Our goal is to develop multiple products based on the ability of phage to precisely target components of the microbiome and on our ability to screen, identify and combine different phage, both naturally occurring and created using synthetic engineering, to develop these treatments.

***Our Product Pipeline***

The chart below identifies our product candidates' pipeline, their current status and expected timing for the upcoming milestones. We do not have any products approved or available for sale, our product candidates are still in the preclinical and clinical development stages, and we have not generated any revenue from product sales.




*(1) In November 2020, we announced the consolidation of our IBD and PSC programs to develop one broad host range product candidate for both IBD and PSC, designated BX003 (replacing a previous phage product candidate for IBD named BX002)*

BX004 – Treatment of Cystic Fibrosis

BX004 is our therapeutic phage product candidate under development for chronic respiratory infections caused by *Pseudomonas aeruginosa,* or *P. aeruginosa,* a main contributor to morbidity and mortality in patients with CF. Enhanced resistance to antibiotics develops, particularly in CF patients, due to extensive drug use consisting of prolonged and repeated broad-spectrum antibiotic courses often beginning in childhood, and leading to the appearance of multidrug-resistant strains. In preclinical *in vitro* studies, BX004 was shown to be active against antibiotic resistant strains of *P. 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.

The Phase 1b/2a trial in CF patients with chronic respiratory infections caused by *P. aeruginosa.* will be comprised of two parts. Part 1 will evaluate the safety, pharmacokinetics and microbiologic/clinical activity of BX004 in eight CF patients in a single ascending dose and multiple ascending dose design. The study design is based on recommendations from the Cystic Fibrosis Therapeutic Development Network. Results from Part 1 are expected in the third quarter of 2022. Part 2 of the Phase 1b/2a trial will evaluate the safety and efficacy of BX004 in 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 are expected by the first quarter of 2023.

In September 2021, the FDA allowed us to initiate the Phase 1b/2a trial of BX004 in CF patients with chronic respiratory infections caused by P. aeruginosa.

In January 2022, we announced that we received an award of up to $5 million from the Cystic Fibrosis Foundation, or CF Foundation, in two tranches. The first tranche of $3 million, was received on December 21, 2021, as an equity investment. Upon completion of patient dosing in Part 1 of our Phase 1b/2a study of BX004 we will have the right to receive the second tranche of $2 million, also as an equity investment. The funding provided by the CF Foundation will be used to support the development of BX004.

BX005 – Treatment of Atopic Dermatitis

BX005 is our topical phage product candidate targeting *Staphylococcus aureus*, or *S. aureus*, a bacterium associated with the development and exacerbation of inflammation in atopic dermatitis. *S. aureus* is more abundant on the skin of atopic dermatitis patients than on the skin of healthy individuals and on lesional skin than non-lesional skin. It also increases in abundance, becoming the dominant bacteria, when patients experience flares. By reducing the load of *S. aureus*, BX005 is designed to shift the skin microbiome composition to its 'pre-flare' state and potentially provide a clinical benefit. In preclinical *in vitro* studies, BX005 was shown to eradicate over 90% of strains, including antibiotic resistant strains, from a panel of *S. aureus* strains (120 strains isolated from skin of subjects from the U.S. and Europe).

In October 2021, we entered into a stock purchase agreement with a subsidiary of Maruho Co. Ltd., or Maruho, a leading dermatology-focused pharmaceutical company in Japan, pursuant to which we issued to Maruho 375,000 shares of our common stock, par value $0.0001 per share, or Common Stock, at a price of $8.00 per share for gross proceeds of $3 million. We also granted Maruho a right of first offer to license BX005, in Japan. The right of first offer will commence following the availability of results from the Phase 1/2 study expected in the fourth quarter of 2022.

BX003 – Treatment of IBD and PSC

On November 12, 2020, we announced consolidation of our IBD and PSC programs into a single broad host range product candidate, named BX003, under development for both indications. Prior to November 2020, we had two separate phage product candidates for IBD and for PSC, with our IBD product candidate named BX002 and PSC product candidate named BX003. After the consolidation, the BX003 product candidate was under development to treat both IBD and PSC, targeting bacterial strains of *Klebsiella pneumoniae*, or *K. pneumoniae*, a potential pathogen implicated in both diseases. *K. pneumoniae* strains isolated from IBD patients were shown to be pro-inflammatory in animal models and may have a role in the onset and aggravation of the disease. Strains of *K. pneumoniae* isolated from PSC patients were shown to cause an inflammatory response in the liver of animal models and were shown to induce the formation of pores through monolayer colonic organoid cultures. Prior to the consolidation, our Phase 1a clinical study was conducted only on BX002, and future clinical studies are planned to be conducted on BX003.

On February 2, 2021, we announced positive results of a randomized, single-blind, multiple-dose, placebo-controlled Phase 1a pharmacokinetic study of BX002, our product candidate for IBD and PSC, conducted under an investigational new drug application, or IND, submitted to the FDA. The study evaluated the safety and tolerability of orally administered BX002 in 18 healthy volunteers. Subjects were randomized to receive orally either BX002 or placebo, twice daily for three days. Subjects were monitored for safety for seven days in a clinical unit, with follow-up for safety assessments done at 14 and 28 days after completion of dosing. BX002 was demonstrated to be safe and well-tolerated, with no serious adverse events and no adverse events leading to discontinuation. In addition, the study met its objective of delivering high concentrations of viable phage to the gastrointestinal tract of approximately $10^{10}$ PFU, or plaque forming units. This equals approximately 1,000 times more viable phage compared to the bacterial burden of *K. pneumoniae* in IBD and PSC patients as measured in stool. Based on the Phase 1a study results, we plan to advance to a Phase 1b/2a study evaluating the efficacy of BX003 for the reduction of *K. pneumoniae* in individuals that carry the target bacteria.

On November 15, 2021, we announced that we plan to temporarily pause the development efforts in BX003 until early 2023.

CRC

We are also developing synthetically engineered phage designed to target strains of bacteria found in CRC tumors. Our CRC program integrates expertise in identifying and validating associations of specific strains of bacteria with human disease and synthetic biology capabilities enabling design of phage that are expected to deliver therapeutic payloads to tumors. Only a small percentage of the new cases of CRC respond to immunotherapy. This lack of response is believed to be due to the lack of novel tumor antigens and scarcity of immune cells in colorectal tumors. We have observed *in vitro* and *in vivo* that phage can be used to target strains of *Fusobacterium nucleatum*, a bacterial species that is highly enriched in colorectal tumors and is believed to be pathogenic. We plan to use phage intravenously to deliver payload genes, such as those encoding immunostimulatory proteins, to tumors while also leading to eradication of these bacteria. We have successfully engineered an IL-15 gene payload into *F. nucleatum* phage. On November 15, 2021, we announced that we plan to temporarily pause the development efforts in CRC until early 2023.

BX001 – Treatment of acne

We developed BX001, our product candidate to modify the appearance of skin in a range of skin types, including oily and acne-prone skin. BX001 is a topical gel that includes a combination of naturally occurring phage that specifically target *Cutibacterium acnes,* or *C. acnes*.

On March 31, 2020, we announced positive topline results from a 4-week randomized, double-blind, dose-finding, placebo-controlled single center Phase 1 cosmetic clinical study of BX001. The 75 enrolled individuals with mild-to-moderate acne were randomized into one of three cohorts: a high dose cohort, a low dose cohort, and a placebo cohort (vehicle). The study met its primary endpoints of safety and tolerability for both doses of BX001, in addition to demonstrating a statistically significant (p=0.036) reduction of C. acnes levels for the high dose of BX001 compared to placebo.

On October 18, 2021, we announced the results of a Phase 2 clinical study of BX001. The study was a 12-week randomized, single center, double-blind, placebo-controlled trial in 140 women with mild-to-moderate acne vulgaris. Subjects were randomized into two cohorts: BX001 or placebo in a 1:1 ratio and self-administered BX001 or placebo twice daily. Key endpoints from the study evaluated the safety, tolerability and efficacy of BX001. BX001 was well-tolerated with no treatment-related adverse events. A statistically significant improvement from baseline was observed in appearance of acne-prone skin but no meaningful difference was demonstrated relative to the placebo arm of the Study. Following such results we decided not to continue pursuing this program.

***Our Strategy***

Our goal is to develop multiple products based on the ability of phage to precisely target components of the microbiome and on our ability to screen, identify and optimally combine different phage, both naturally occurring and generated using synthetic engineering, to develop these treatments. We intend to continue to:

- Investigate clinical safety and efficacy of our lead phage-based product candidates in CF and AD, as well as in IBD/PSC;
- Identify new pathogenic bacteria to be targeted by phage therapy for our existing indications and possible new indications;
- Develop and partner microbiome-based biomarker tests, based on our proprietary XMarker platform, that can be used for disease diagnosis or as companion diagnostics; and
- Evaluate the preclinical activity of our synthetic engineering approach for delivering therapeutic payloads to bacteria that are resident within CRC tumors followed by evaluation through clinical testing.

***Our phage discovery platform***

Our approach is driven by the convergence of several factors: a rapidly increasing understanding of phage, including the links between phage behaviors and their genomes; growing evidence that the presence of specific harmful bacteria may impact chronic diseases, such as CF, making them in principle, amenable to treatment with phage; and by a growing number of anecdotal reports from different academic centers of successful compassionate use of phage to treat seriously ill patients who were unresponsive to other therapies. We believe our phage therapeutic product candidates have the potential to treat conditions and diseases by precisely targeting pathogenic bacteria without disrupting elements of the healthy microbiota.

Our phage-based product candidates are developed utilizing our proprietary research and development platform named BOLT. The BOLT platform is unique, employing cutting edge methodologies and capabilities across disciplines including computational biology, microbiology, synthetic engineering of phage and their production bacterial hosts, bioanalytical assay development, manufacturing and formulation, to allow agile and efficient development of natural or engineered phage combinations, or cocktails.

BOLT is designed to allow rapid phage cocktails. The BOLT cocktail targets a broad patient population and may be comprised of naturally-occurring or synthetically engineered phage. The cocktail contains phage with complementary features and is further optimized for multiple characteristics such as broad target host range, ability to prevent resistance, biofilm penetration, stability and ease of manufacturing. Development of the optimized phage cocktail is anticipated to require 1-2 years.

We combine multiple technologies that originate from the laboratories of our scientific founders and that were developed internally. Technologies that were developed by its scientific founders are described in leading scientific journals. One of our scientific founders, Professor Rotem Sorek, a Professor in the Department of Molecular Genetics at the Weizmann Institute of Science, or WIS, is a world leader in phage genomics and bacterial defense mechanisms. Another scientific founder, Professor Eran Elinav, a Professor in the Department of Immunology at the WIS, is an expert in investigating the link between the microbiome and human health and disease. Our third scientific founder, Professor Timothy K. Lu, is a world leader in synthetic biology approaches to engineering gene circuits and phage, leading the Synthetic Biology Group in the Department of Electrical Engineering and Computer Science and the Department of Biological Engineering at the Massachusetts Institute of Technology, or MIT. In addition, through the acquisition of the privately held Israel-based company, RondinX Ltd. in 2017, we gained access to high throughput genomic analyses techniques developed by Professor Eran Segal, a leading computational biologist from the Department of Computer Science and Applied Mathematics at the WIS. The combination of the technologies and expertise from these leaders in each of their respective fields is critical in enabling us to focus on treating complex human diseases and conditions by precise manipulation of the microbiome.

***Manufacturing***

We have developed a manufacturing process that utilizes state of the art industrial methods for the manufacturing of our product candidates. This process is designed to comply with current Good Manufacturing Practice, or cGMP, with the appropriate scale to meet our clinical study needs, and to fulfill the requirements of regulators for human studies. We currently operate a manufacturing model that combines an in-house process development and manufacturing suite with the flexibility to outsource to third-party manufacturing organizations when needed. As such, for BX004 we have engaged an additional third-party provider to supplement our in-house process development activities. We have selected this organization based on its experience, capability, capacity and regulatory status. Projects are managed by a specialist team of our internal staff, who assure compliance with the technical aspects and regulatory requirements of the manufacturing process.

We maintain service agreements with multiple manufacturers. These service agreements generally are short-term in nature and can be extended or renewed. The production amounts identified in our current service agreements are sufficient to support our current clinical study needs.

In March 2021, we moved into a new 6,500 square foot manufacturing facility in our headquarters, in Ness Ziona, Israel. Our facility is designed with the capacity to produce clinical quantities of our product candidates required for future early-stage clinical development. Our facility consists of two suites for drug substance phage production/development as well as formulation and final drug product production rooms to support topical, oral, inhaled and injectable phage-based products in a liquid, cream, semi-solid or dry form.

While we do not have a current need for a commercial scale manufacturing capacity, at the appropriate time we intend to evaluate building large scale cGMP internal manufacturing capabilities, which may include expansion of our operations.

***Intellectual Property***

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patent protection in the United States and internationally for our product candidates and discovery platform. We also rely on trademarks, trade secrets, know-how, copyrights, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. For more information regarding the risks related to our intellectual property, see "*Risk Factors — Risks Related to our Licensed and Co-Owned Intellectual Property.*"

We plan to continue to expand our intellectual property estate by filing patent applications directed to formulations, related methods of treatment, methods of manufacture or identification from our ongoing development of our product candidates, as well as discovery based on our proprietary product platform. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend, and enforce any patents that we may obtain, preserve the confidentiality of our trade secrets and know-how and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of its patent applications or the first to file patent applications covering such subject matter, and we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention.

*Patent portfolio*

Our patent portfolio consists of owned patent applications, as well as both licensed and co-owned patent applications (that are also licensed). See "*Risk Factors — Risks Related to our Licensed and Co-Owned Intellectual Property.*" For some of these applications, prosecution has not started, and others are in the early stages of prosecution in the United States and in selected jurisdictions outside of the United States. We solely own four patent families. We co-own one international patent family (United States, Europe, Australia, Canada, China and Japan with Keio University in Tokyo, Japan, or Keio, one international patent family (United States, Australia, Brazil, Canada, China, Japan, Israel, European Patent Office, Korea and India national filings) with Yeda Research and Development Company Limited, or Yeda, and one international patent family (United States, Europe, Australia, Canada, China and Japan) with both Keio and Yeda. We have an exclusive license from Yeda and Keio for these co-owned patent applications. We have exclusive licenses from Yeda, Keio, or MIT for the rest of the patents and patent applications in its portfolio.

A significant portion of our portfolio is directed to our product candidates, specifically: CF, AD, IBD, PSC and CRC, as well as to our bacterial target discovery and bacteriophage discovery technology platforms. Prosecution has yet to commence for most of the pending patent applications covering our product candidates. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO are often significantly narrowed by the time they issue, if they issue at all. We expect this to be the case with respect to our licensed and co-owned patent applications, described briefly below.

*CF*

We solely own one patent family (PCT stage) containing claims directed to pharmaceutical compositions comprising combinations of bacteriophage to treat chronic Pseudomonas lung infections, especially common in CF patients, methods of use for these bacteriophage combinations, and methods of identifying patients who will respond to these bacteriophage combinations. Any United States patents issuing from the pending application covering our lead bacteriophage combination in this program, if issued, are expected to expire in 2042. Patent term adjustments or patent term extensions could result in later expiration dates.

*AD*

We solely own one patent family (pre-PCT stage) containing claims directed to pharmaceutical compositions comprising combinations of bacteriophage to treat skin infections, especially common in AD patients, methods of use for these bacteriophage combinations, and methods of identifying patients who will respond to these bacteriophage combinations. Any United States patents issuing from the pending application covering our lead bacteriophage combination in this program, if issued, are expected to expire in 2042. Patent term adjustments or patent term extensions could result in later expiration dates.

*IBD*

We solely own one patent family (PCT stage), co-own with Keio one international patent family (United States, Europe, Australia, Canada, China and Japan) and co-own with Keio and Yeda one international patent family (United States, Europe, Australia, Canada, China and Japan), containing claims directed to pharmaceutical compositions comprising combinations of bacteriophage useful to treat IBD and other diseases of the gastrointestinal tract, methods of use for these bacteriophage combinations, methods of identifying patients who will respond to these bacteriophage combinations, and methods of treating IBD by targeting bacterial strains discovered to cause or contribute to that disease.

We also have an exclusive license from Keio for an international patent family including patent applications in the United States, Australia, Canada, China, Europe and Japan. These applications are directed to methods of use for these bacteriophage combinations, methods of identifying patients who will respond to these bacteriophage combinations, and methods of treating IBD by targeting a bacterial strain discovered to cause or contribute to that disease. Any United States patents issuing from the pending applications covering our lead bacteriophage combination in this program, if issued, are expected to expire in 2037, 2038 or 2042. Patent term adjustments or patent term extensions could result in later expiration dates.

*PSC*

We have an exclusive license to one United States national patent application and two Japanese patent applications with claims directed to pharmaceutical compositions comprising bacterial strains discovered to be beneficial in the treatment of PSC and methods of using the same, and to methods of treating PSC by reducing the level of certain bacterial strains discovered to contribute to PSC. Any United States patents issuing from the pending applications in this program, if issued, are expected to expire in 2038 or 2039. Patent term adjustments or patent term extensions could result in later expiration dates.

*CRC*

We solely own one patent family (PCT stage), containing claims directed to pharmaceutical compositions and formulations comprising combinations of bacteriophage (both synthetic and naturally occurring) useful to treat cancer. Any U.S. patent issuing from the pending application covering our lead bacteriophage combination in this program, if issued, are expected to expire in 2041. Patent term adjustments or patent term extensions could result in later expiration dates.

*Acne*

We co-own with Yeda one international patent family (United States, Australia, Brazil, Canada, China, Japan, Israel, European Patent Office, Korea and India national filings), containing claims directed to pharmaceutical compositions and formulations comprising combinations of bacteriophage useful to treat acne, methods of use for these bacteriophage combinations, and methods of identifying patients who will respond to these bacteriophage combinations. Any United States patents issuing from the pending application covering our lead bacteriophage combination in this program, if issued, are expected to expire in 2038. Patent term adjustments or patent term extensions could result in later expiration dates.

*Technology Platform*

We are exclusively licensed to two United States issued patents, two European Patent Convention applications, and three United States national applications. These licensed patent families include two issued United States patents and multiple pending patent applications, with claims directed to methods of producing recombinant bacteriophage in yeast cells, recombinant bacteriophage with broader or altered host range than the parent strains from which they are derived, and recombinant methods for increasing the lytic efficiency of a bacteriophage. The patents issuing from the pending applications in the United States directed to our platform, if issued, are expected to expire between 2034 and 2038. Patent term adjustments or patent term extensions could result in later expiration dates.

*Patent term*

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file patent applications, including the United States, the base term is 20 years from the filing date of the earliest-filed non-provisional patent application from which the patent claims priority. The term of a United States patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the USPTO. In some cases, the term of a United States patent is shortened by a terminal disclaimer that reduces its term to that of an earlier-expiring patent. The term of a United States patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the patent is granted. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one United States patent that includes at least one claim covering the composition of matter of such an FDA-approved drug, an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or fourteen years from the date of the FDA approval of the drug, and a patent cannot be extended more than once or for more than a single product. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency.

In the future, if and when our product candidates receive FDA approval, we expect to apply, if appropriate, for patent term extension on patents directed to those product candidates, their methods of use and/or methods of manufacture. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

*Trade Secrets and Know-How*

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual's or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of its proprietary information by third parties.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets and benefit from the exclusive use thereof. For more information regarding the risks related to our intellectual property, see "*Risk Factors — Risks Related to Our Licensed and Co-Owned Intellectual Property*."

***Competition***

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, strong competition and an emphasis on proprietary products. While we believe that our technology, knowledge and experience provide us with competitive advantages, we face substantial competition from many different sources, including larger pharmaceutical companies with more resources. Specialty biotechnology companies, academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, time to market, cost, level of promotional activity and intellectual property protection.

We are aware of a number of biotechnology companies developing bacteriophage products to treat diseases. To our knowledge, several biotechnology companies, such as Adaptive Phage Therapeutics, Locus Biosciences, Inc., Armata Pharmaceuticals, Inc. and SNIPR Biome, as well as academic institutions, have discovery stage or clinical programs utilizing naturally occurring phage or synthetic biology approaches. In addition, we are aware of several investigational and marketed products to treat the indications that we are targeting with our product candidates, including, but not limited to:

- *CF:* Trikafta, Symdeco, Pulmozyme, Tobramycin, Aztreonam
- *AD:* Elidel, Eucrisa, Ruxolitinib, Dupixent
- *IBD*: Humira, Stelara, Entyvio, Inflectra and Cimzia
- *PSC*: Obeticholic acid (Intercept clinical candidate), GS-9674 (Gilead clinical candidate), BTT1023, (Acorda Therapeutics candidate) and PLN-74809 (Pliant clinical candidate)

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than ours and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than us in discovering product candidates, obtaining approval for such product candidates and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

These third parties compete with us in recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our program.

***Sales and Marketing***

We intend to pursue the commercialization of our drug product candidates either by building internal sales and marketing capabilities or through collaborations with others.

In October 2021, we entered into a stock purchase agreement with a subsidiary of Maruho, a leading dermatology-focused pharmaceutical company in Japan, pursuant to which we issued to Maruho 375,000 shares of our Common Stock, at a price of $8.00 per share for gross proceeds of $3 million. We also granted Maruho a right of first offer to license BX005 in Japan. The right of first offer will commence following the availability of results from the Phase 1/2 study expected in the fourth quarter of 2022.

***Government Regulation***

Government authorities in the United States and other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety, efficacy, purity, and/or potency must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority where the product is intended to be marketed.

**U.S. Biological Product Development Process**

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with applicable U.S. requirements at any time during the product development, approval, or post-marketing process may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval or license revocation, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Certain of our current product candidates and future product candidates must be approved by the FDA through a Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements, if needed;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety, purity, potency and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a BLA;
- A determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;

- Potential FDA audit of the clinical trial sites that generated the data in support of the BLA;
- Payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States.

**Preclinical Studies and IND**

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to establish a rationale for therapeutic use and in some cases to assess the potential for adverse events. The conduct of preclinical studies is subject to federal regulations and requirements, including in some cases GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and, must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

**Clinical Trials**

Clinical trials involve the administration of the biological product candidate to healthy volunteers or disease-affected patients under the supervision of qualified investigators, generally physicians not employed by, or under, the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and efficacy, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and sometimes further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for labeling for new drugs.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are conducted to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

It is possible for Phase 1, Phase 2, Phase 3 and other types of clinical trials not to be completed successfully within a specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies may complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

**FDA Review Process**

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses, and also meets the regulatory requirements for potency and purity. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy in the intended indication, purity and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States. Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information rather than accept the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such a decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

After the FDA evaluates a BLA, it will issue an approval letter, or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor's interpretation of the same data.

**Orphan Drug Designation**

Under the Orphan Drug Act of 1983, or the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation for a biologic must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity.

**Expedited Development and Review Programs**

The FDA has a fast-track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Any product submitted to the FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA generally requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Products receiving accelerated approval may be subject to expedited withdrawal procedures if such clinical trials fail to verify the predicted clinical benefit or if the sponsor fails to conduct such trials in a timely manner.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast-track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

**Pediatric Information**

Under the Pediatric Research Equity Act of 2003, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

**Post-marketing Requirements**

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations, which require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

**Biosimilars and Exclusivity**

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials.

Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States, available under the Best Pharmaceuticals for Children Act by way of its application to biologics through the Biologics Price Competition and Innovation Act. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods, which must be in place in order for pediatric exclusivity to apply. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA issued “Written Request” for such a trial, although FDA may issue such a Written Request at the request of the sponsor.

**Companion Diagnostics**

We may employ companion diagnostics to help it to more accurately identify patients within a particular bacterial strain, both during our clinical trials and in connection with the commercialization of our product candidates that we are developing or may in the future develop. Companion diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA and, as such, require either clearance or approval prior to commercialization. The level of risk combined with available controls to mitigate risk determines whether a companion diagnostic device requires Premarket Approval Application approval or is cleared through the 510(k) premarket notification process. For a novel therapeutic product for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and approved or 510(k)-cleared contemporaneously with the therapeutic. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product.

**Government Regulation Outside of the United States**

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials of drug products as well as the approval, manufacture and distribution of our product candidates. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

**Clinical Trials**

Certain countries outside of the United States have a regulatory process similar to the U.S process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application, or CTA, must be submitted for each clinical trial to the national health authority and an independent ethics committee in each country in which the trial is to be conducted, much like the FDA and an IRB, respectively. CTAs must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the Clinical Trials Directive (and corresponding national laws of the member states) and further detailed in applicable guidance documents. Once the CTA is approved in accordance with a country's requirements, the clinical trial may proceed. A similar process to the one described for the European Union is required in Israel for initiation of clinical trials. The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

**Approval Process**

In order to market our products, we must obtain a marketing approval for each product and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing in comparison to the testing carried out for the U.S. approval. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally is subject to all of the same risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country.

To obtain marketing approval of a medicinal product under the European Union regulatory system, an applicant must submit a marketing authorization application, or MAA, under either a centralized or a decentralized procedure. The decentralized procedure is based on a collaboration among the member states selected by the applicant. In essence, the applicant chooses a 'lead' member state that will carry out the scientific assessment of the MAA and review the product information. The other member states must recognize the outcome of such assessment and review except in case of a "serious potential risk to public health." The decentralized procedure results in the grant of a national marketing authorization in each selected country. That procedure is available for all medicinal products unless they fall into the mandatory scope of the centralized procedure. In practice, it is used for OTC, not highly innovative products, generic products and, increasingly, for biosimilars.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for certain medicinal products, including for medicinal products produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products, or ATMPs, and products with a new active substance and indicated for the treatment of certain diseases. For products with a new active substance and indicated for the treatment of other diseases, products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure is optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or CHMP, the main scientific committee established at the European Medicines Agency, or EMA, is responsible for conducting the scientific assessment of the future medicinal product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. The maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops. The European Commission grants or refuses the marketing authorization, following a procedure that involves representatives of the member states. The European Commission's decision is in accordance with the CHMP scientific assessment except in very rare cases.

Pursuant to Regulation (EC) 1394/2007, specific rules apply to ATMPs, a category that is comprised of gene therapy medical products, somatic cell therapy medicinal products, and tissue-engineered medicinal products. Those rules have triggered the adoption of guidelines on manufacturing, clinical trials and pharmacovigilance that adapt the general regulatory requirements to the specific characteristics of ATMPs. Regulation (EC) 1394/2007 introduced a "hospital exemption." which authorizes hospitals to develop ATMP for their internal use without having obtained a marketing authorization and to complying with European Union pharmaceutical law. The hospital exemption, which is in essence a compounded ATMP, has been transposed in all Member States, sometimes in such a way that the ATMPs under the hospital exemption are competitive alternatives to ATMPs with marketing authorization. The broad use of the hospital exemption by national hospitals led the European Commission to discuss with the Member States a more reasonable application of the hospital exemption that would not undermine the common legal regime for ATMP.

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional renewal. Any authorization which is not followed by the actual placing of the medicinal product on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

**Orphan Designation**

Countries other than the United States have adopted a specific legal regime to support the development and marketing of drugs and biologics for rare diseases.

For example, in the European Union, Regulation 141/2000 organizes the grant of orphan drug designations to promote the development of products that are intended for the diagnosis, prevention or treatment of life threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Economic Area (the European Union, plus Iceland, Liechtenstein and Norway), or EEA, (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized or, if a method exists, the product would be of significant benefit to those affected. The EMA's Committee for Orphan Medicinal Products, or COMP, examines if the orphan criteria are met and gives opinions thereon, and the orphan status is granted by the European Commission. The meeting of the criteria for orphan designation is examined again by the COMP at the time of approval of the medicinal product, which typically occurs several years after the grant of the orphan designation. If the criteria for orphan designation are no longer met at that time, the European Commission withdraws the orphan status.

In the European Union, orphan drug designation entitles the sponsor to financial incentives such as reduction of fees or fee waivers and to ten years of market exclusivity granted following medicinal product approval. Market exclusivity precludes the EMA or a national regulatory authority from validating another MAA, and the European Commission or a national regulatory authority from granting another marketing authorization, for a same or similar medicinal product and a same therapeutic indication, for that time period. This 10-year period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. The orphan exclusivity may be lost vis-à-vis another medicinal product in cases the manufacturer is unable to assure sufficient quantity of the medicinal product to meet patient needs or if that other product is proved to be clinically superior to the approved orphan product. A drug is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug designation must be requested before submitting a MAA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, and it does not afford any regulatory exclusivity until a marketing authorization is granted.

**Expedited Development and Approval**

Mechanisms are in place in many jurisdictions that allow an earlier approval of the drug so that it reaches patients with unmet medical needs earlier. The European Union, for example, has instituted several expedited approval mechanisms including two mechanisms that are specific to the centralized procedure:

- the accelerated approval: the EMA may reduce the maximum timeframe for the evaluation of an MAA from 210 days to 150 days when the future medicinal product is of major interest from the point of view of public health, in particular from the viewpoint of therapeutic innovation.

- the conditional marketing authorization: as part of its marketing authorization process, the European Commission may grant marketing authorizations on the basis of less complete data than is normally required.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk/benefit balance of the medicinal product is positive;

- it is likely that the applicant will be in a position to provide the comprehensive clinical data;

- unmet medical needs will be addressed; and

- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required.

The granting of a conditional marketing authorization is typically restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may however be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public health threats.

Conditional marketing authorizations are valid for one year, on a renewable basis. The conditions to which approval is subject will typically require the holder to complete ongoing trials or to conduct new trials with a view to confirming that the benefit-risk balance is positive and to collect pharmacovigilance data. Once the conditions to which the marketing authorization is subject are fulfilled, the conditional marketing authorization is transformed into a regular marketing authorization. If, however, the conditions are not fulfilled with the timeframe set by EMA, the conditional marketing authorization ceases to be renewed.

The EMA has also implemented the so-called “PRIME” (PRIority MEdicines) status in order support the development and accelerate the approval of complex innovative medicinal products addressing an unmet medical need. PRIME status enables early dialogue with the relevant EMA scientific committees and, possibly, some payors and thus reinforces the EMA’s scientific and regulatory support. It also opens accelerated assessment of the MAA as PRIME status, is normally reserved for medicinal products that may benefit from accelerated assessment, i.e., medicines of major interest from a public health perspective, in particular from a therapeutic innovation perspective.

Finally, all medicinal products (i.e. decentralized and centralized procedures) may benefit from an MA “under exceptional circumstances.” This marketing authorization is close to the conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike the conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. The risk-benefit of the medicinal product is reviewed annually. As a result, although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization is withdrawn in case the risk-benefit ratio is no longer favorable.

**Pediatrics**

Mandatory testing in the pediatric population is required in more and more jurisdictions. The European Union has enacted a complex and very stringent system that has inspired other jurisdictions, including the United States and Switzerland. Any application for approval of (i) a medicinal product containing a new active substance or (ii) a new therapeutic indication, pharmaceutical form or route of administration of an already authorized medicinal product which contains an active substance still protected by a supplementary protection certificate, or SPC, or a patent that qualifies for an SPC, must include pediatric data. Otherwise, the application is not validated by the competent regulatory authority. The submission of pediatric data is mandatory in those cases, even if the application concerns an adult use. Submission of pediatric data is not required or fully required if the EMA granted, respectively, a full or partial waiver to pediatric development. Moreover, that submission can be postponed if the EMA grants a deferral in order not to delay the submission of the MAA for the adult population.

The pediatric data are generated through the implementation of a pediatric investigation plan, or PIP, that is proposed by the company after completion of the PK studies in adults and agreed upon by the EMA, typically after some modifications. The PIP lists all the studies to conduct and measures to take in order to prove the safety and efficacy of the future medicinal product when used in children. The EMA may agree to modify the PIP at the company's request. The scope of the PIP is the adult therapeutic indication or the condition of which the adult application is part or even the mechanism of action of the active substance, at the EMA's quasi-discretion. This very broad discretion enables the EMA to require companies to develop children indications that are different from the adult indications.

Completion of a PIP renders the company eligible for a pediatric reward, which can be six-month extension of the term of the SPC or, in the cases of orphan medicinal products, two additional years of market exclusivity. The reward is subject, among other conditions, to the PIP being fully completed, to the pediatric medicinal product being approved in all the member states, and to the results of the pediatric studies being mentioned, in one way or another (for example, the approval of a pediatric indication), in the summary of product characteristics of the product.

**Post-Marketing Requirements**

Many countries impose post-marketing requirements similar to those imposed in the United States, in particular safety monitoring or pharmacovigilance. In the European Union, pharmacovigilance data are the basis for the competent regulatory authorities imposing the conduct of post-approval safety or efficacy study, including on off-label use. Non-compliance with those requirements can result in significant financial penalties as well as the suspension or withdrawal of the marketing authorization.

**Supplementary Protection Certificate and Regulatory Exclusivities**

In some countries other than the United States, some of our patents may be eligible for limited patent term extension, depending upon the timing, duration and specifics of the regulatory approval of our product candidates and any future product candidates. Furthermore, authorized drugs and biologics may benefit from regulatory exclusivities (in additional to patent protection resulting from patents).

In the European Union, Regulation (EC) 469/2009 institutes SPCs. An SPC is an extension of the term of a patent that compensates for the patent protection lost because of the legal requirements to conduct safety and efficacy tests and to obtain a marketing authorization before placing a medicinal product on the market. An SPC may be applied for any active substance that is protected by a "basic patent" (a patent chosen by the patent holder, which can be a product, process or application patent) and has not been placed on the market as a medicinal product before having obtained a marketing authorization in accordance with European Union pharmaceutical law. The term of the SPC is maximum five years, and the combined patent and SPC protection may not exceed fifteen years from the date of the first marketing authorization in the EEA. SPC rights are restricted by both the basic patent and the marketing authorization, i.e., the SPC grants the same rights as those conferred by the basic patent but limited to the active substance covered by the marketing authorization (and any use as medicinal product approved afterwards).

While SPC are regulated at the European level, they are granted by the national patent offices. The grant of an SPC requires a basic patent granted by the national patent office and a marketing authorization, which is the first marketing authorization for the active substance as a medicinal product in the country. Furthermore, no SPC must have already been granted to the active substance, and the application for the SPC must be filed with the national patent office within six months of the first marketing authorization in the EEA or the grant of the basic patent, whichever is the latest.

In the future, we may apply for an SPC for one or more of our currently owned or licensed European patents to add patent life beyond their current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant MAA.

Furthermore, in the European Union, medicinal products may benefit from the following regulatory exclusivities: data exclusivity, market protection, market exclusivity, and pediatric reward.

A medicinal product that contains a new active substance (reference medicinal product) is granted eight years of data exclusivity followed by two years of market protection. Data exclusivity prevents other companies from referring to the non-clinical and clinical data in marketing authorization dossier of the reference medicinal product for submission of generic MAA purposes, and market protection prevents other companies from placing generics on the market. Pursuant to the concept of global marketing authorization, any further development of that medicinal product (e.g., new indication, new form, change to the active substance) by the marketing authorization holder does not trigger any new or additional protection. The authorization of any new development is considered as "falling" into the initial marketing authorization with regard to regulatory protection; hence, the new development only benefits from the regulatory protection that remains when it is authorized. The only exception is a new therapeutic indication that is considered as bringing a significant clinical benefit in comparison to the existing therapies. Such new indication will add one-year of market protection to the global marketing authorization, provided that it is authorized within the first eight years of authorization (i.e., during the data exclusivity period). Moreover, a new therapeutic indication of a "well-established substance" benefits from one-year data exclusivity but limited to the non-clinical and clinical data supporting the new indication. Any active substance approved for at least ten years in the EEA qualifies as well-established substance.

Biosimilars may be approved through an abbreviated approval pathway after the expiration of the eight-year data exclusivity period and may be marketed after the 10 or 11-year market protection period. The approval of biosimilars requires the applicant to demonstrate similarity between the biosimilar and the biological medicinal product and to submit the non-clinical and clinical data defined by the EMA. The biosimilar legal regime has been mainly developed through EMA's scientific guidelines applicable to categories of biological active substances. Unlike in the United States, interchangeability is regulated by each member state.

Market exclusivity is a regulatory protection exclusively afforded to medicinal products with an orphan status. Market exclusivity precludes the EMA or a national regulatory authority from validating another MAA, and the European Commission or a national regulatory authority from granting another marketing authorization, for a same or similar medicinal product and a same therapeutic indication, for a period of ten years from approval (see above).

Pediatric reward is another regulatory exclusivity. Completion of a PIP renders the company eligible for a pediatric reward, which can be six-month extension of the term of the SPC or, in the cases of orphan medicinal products, two additional years of market exclusivity (see above). In case a PIP is completed on a voluntary basis, i.e., for an approved medicinal product that is not or no longer protected by an SPC or a basic patent, the pediatric reward takes the form of a "pediatric use marketing authorization", or PUMA. That special authorization does not fall into the global marketing authorization and thus benefits from eight years of data exclusivity followed by two or three years of market protection.

**Other U.S. Healthcare Laws and Compliance Requirements**

In addition to FDA restrictions on the marketing of pharmaceutical products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our business or financial arrangements and relationships through which we market, sell and distribute the products, if any, for which we obtain approval. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute;

- federal civil and criminal false claims laws and civil monetary penalties laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;

- the civil monetary penalties law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal transparency requirements under the Affordable Care Act, or ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is mainly governed by the national anti-bribery laws of the member states, such as the UK Bribery Act 2010, or national anti-kickback provisions (France, Belgium, etc.). Infringement of these laws could result in substantial fines and imprisonment. In certain member states, payments made to physicians must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

**Additional Regulation**

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

**U.S. Foreign Corrupt Practices Act**

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Similar rules apply to many other countries worldwide such as France ("*Loi Sapin"*) or the United Kingdom (UK Bribery Act).

**U.S. Healthcare Reform**

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been a number of significant changes to the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

In addition, the Budget Control Act of 2011 and the Bipartisan Budget Act of 2015 led to aggregate reductions of Medicare payments to providers of 2% per fiscal year that will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional Congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

**Coverage and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United Sates, cosmetics are not generally eligible for coverage and reimbursement and thus any products that are marketed as cosmetics will not be covered or reimbursed. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our products could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate.

As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product, we may need to conduct expensive clinical trials in order to demonstrate the medical necessity and cost-effectiveness of such product, in addition to the costs required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

Outside of the United States, the pricing of pharmaceutical products is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from member state to member state. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

**Data Privacy and Security Laws**

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including Health Insurance Portability and Accountability Act of 1996, or HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Protection Act, the California Privacy Rights Act, and the General Data Protection Regulation, or GDPR, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

***Material Agreements***

*License Agreements*

License Agreement with Yeda

On June 22, 2015, BiomX Ltd. entered into the Research and License Agreement, with Yeda, or, as amended, the Yeda 2015 License Agreement, the technology transfer office of the WIS, pursuant to which BiomX Ltd. received an exclusive worldwide license to certain know-how and research information related to the development, testing, manufacturing, production and sale of microbiome-based therapeutic product candidates, including candidates specified in the agreement, which are used in our phage discovery platform, as well as patents, research and other rights to phage product candidates resulting from the work of the consultants identified in the agreement and further research conducted at the WIS which BiomX Ltd. funded.

In connection with this license, we are to pay a non-refundable license fee of $10,000 per year. In addition, BiomX Ltd. contributed an aggregate of approximately $2.0 million to the research budget agreed upon in the Yeda 2015 License Agreement. We are also required to pay tiered royalties in the low single digits on net sales of products and diagnostic kits covered by the Yeda 2015 License Agreement, subject to reductions as described therein. The products and diagnostic kits covered by the license agreement include those directed to IBD, CRC, and any other indications that may be treated by phage-based therapies, as well as related technology platforms. If we sublicense our rights under this agreement we will be obligated to pay Yeda additional sublicense royalties expressed as a percentage of the sublicensing receipts described in the agreement received ranging from the mid-teens to the mid-twenties. We are obligated to pay filing and maintenance expenses in respect of patents licensed under the Yeda 2015 License Agreement. In connection with the Yeda 2015 License Agreement, BiomX Ltd. also issued certain ordinary shares which were subsequently converted to 193,406 shares of our Common Stock as part of the Business Combination (as defined below). In the event of certain mergers and acquisitions we are party to, we are obligated to pay Yeda an amount equivalent to 1% of the consideration received under such transaction.

Unless terminated earlier by either party, the license granted will remain in effect in each country and for each product developed based on the license until the later of the expiration of the last licensed patent (which is expected to be in 2039) in such country for such product, and eleven years from the date of first commercial sale of such product in such country for such product. The Yeda 2015 License Agreement terminates upon the later of the expiration of the last of the patents covered under the agreement, and the expiry of a continuous 15-year period during which there has not been a first commercial sale of any product in any country. Yeda may also terminate the agreement if we fail to observe certain diligence and development requirements and milestones as described in the agreement. We or Yeda may terminate the agreement for the material uncured breach of the other party after a notice period, or the other party's winding up, bankruptcy, insolvency, dissolution or other similar discontinuation of business. Upon termination of the agreement, other than due to the passage of time, we are required to grant to Yeda a non-exclusive, irrevocable, perpetual, fully paid-up, sublicensable, worldwide license in respect of our rights in know-how and research results as described in the Yeda 2015 License Agreement, provided that if Yeda subsequently grants a license to a third party that utilizes our rights, we are entitled to share in the net proceeds actually received by Yeda arising out of that license, subject to a cap based on the development expenses that we incur in connection with the Yeda 2015 License Agreement.

We consult with Yeda with respect to patent prosecution and maintenance decisions. Yeda is primarily responsible for prosecution and maintenance with respect to Licensed Information (as defined in the license) and we are responsible for prosecution and maintenance with respect to Subsequent Results (as defined in the license). We and Yeda are both entitled to consultation rights. We are responsible for costs associated with prosecution and maintenance of all patents and applications.

We are entitled to enforce the patent rights under the license upon approval by Yeda. Yeda may elect to join the lawsuit, but we are responsible for all litigation-related expenses. Yeda reserves the right to bring its own actions if we do not notify Yeda of our intent to enforce a right or bring an action after we initially notified Yeda of the potential action.

Exclusive Patent License Agreement with Keio and JSR Corporation, or JSR, for IBD

BiomX Ltd. entered into an Exclusive Patent License Agreement with Keio, and JSR on December 15, 2017, as amended, pursuant to which BiomX Ltd. was granted an exclusive, royalty-bearing, worldwide, perpetual sublicense by JSR to certain patent rights related to our IBD program. Specifically, these patent rights relate to bacterial targets that have been observed to be related to IBD and the phage that were observed to eradicate these bacterial targets.

We paid JSR a license issue fee of $10,000 and have agreed to pay annual fees ranging from $15,000 to $25,000 in each subsequent year. In addition to the license fees, we have agreed to make payments upon the satisfaction of certain clinical and regulatory milestones up to an aggregate of $3.2 million, of which $40,000 was paid in February 2021. We are also required to pay tiered royalties expressed as a percentage of annual net sales of products developed under the agreement in the low single digits. If we sublicense our rights under this agreement, we will be obligated to pay sublicense royalties expressed as a percentage of sublicense income received, including any license signing fee, license maintenance fee, distribution or joint marketing fee and milestone payments, ranging in the high single digits to the low teens. Our payments under this agreement are subject to reductions as set forth therein.

Unless earlier terminated, this agreement will expire on the later of the date on which all issued patents and filed patent applications have expired (which is expected to be in 2039), or been abandoned, withdrawn, rejected, revoked or invalidated, and five years from the date of first commercial sale of a product developed under the agreement in any country or, if later, when the product ceases to be covered by a valid claim in the United States, European Union or Japan. JSR may terminate this agreement if we fail to pay the amounts due under this agreement, or upon our winding up, bankruptcy, insolvency, dissolution or other similar discontinuation of business, or if we breach the material terms of this agreement and such breach is uncured. We may terminate this agreement at any time upon three months' advance written notice to JSR.

We, Keio and JSR are responsible for maintenance and prosecution of patents that are to be jointly owned by the parties. JSR is entitled to the opportunity to advise and approve decisions that would have a material adverse impact on the scope of the claims. JSR is responsible for patents that are listed in such agreement and we are entitled to advise with respect to patent counsel, scope of claims, and other matters. We are entitled to bring enforcement actions (in our name alone and at our own expense). We are required to obtain JSR's prior written consent for each action we bring with respect to the Patent Rights only.

Exclusive Patent License Agreement with Keio and JSR for PSC

We entered into an additional Exclusive Patent License Agreement with Keio and JSR on April 22, 2019, pursuant to which we were granted an exclusive, royalty-bearing, worldwide, perpetual sublicense by JSR to certain patent rights related to our PSC program. Specifically, these patent rights relate to bacterial targets that have been observed to be related to PSC and the phage that were observed to eradicate these bacterial targets.

We paid JSR a license issue fee of $20,000 and have agreed to pay annual fees ranging from $15,000 to $25,000 in each subsequent year. In addition to the license fees, we have agreed to make payments upon the satisfaction of certain clinical and regulatory milestones up to an aggregate amount of $3.2 million. We are also required to pay tiered royalties expressed as a percentage of annual net sales of products developed under the agreement in the low single digits. If we sublicense our rights under this agreement, we will be obligated to pay sublicense royalties expressed as a percentage of sublicense income received, including any license signing fee, license maintenance fee, distribution or joint marketing fee and milestone payments, ranging in the high single digits to the low teens. Our payments under this agreement are subject to reductions as set forth therein.

Unless earlier terminated, this agreement will expire on the later of the date on which all issued patents and filed patent applications have expired (which is expected to be in 2039), or been abandoned, withdrawn, rejected, revoked or invalidated, and five years from the date of first commercial sale of a product developed in connection with this agreement in any country or, if later, when the product ceases to be covered by a valid claim in the United States, European Union or Japan. JSR may terminate this agreement if we fail to pay the amounts due under this agreement, or upon our winding up, bankruptcy, insolvency, dissolution or other similar discontinuation of business, or if we breach the material terms of this agreement and such breach is uncured. We may terminate this agreement at any time upon three months' advance written notice to JSR.

We, Keio and JSR are responsible for maintenance and prosecution of patents that are to be jointly owned by the parties. JSR is entitled to the opportunity to advise and approve decisions that would have a material adverse impact on the scope of the claims. JSR is responsible for patents that fall under Patent Rights and we are entitled to advise with respect to patent counsel, scope of claims, and other matters. We are entitled to bring enforcement actions (in our name alone and at our own expense).

**Employees**

As of December 31, 2021, we had 103 full-time employees and consultants and 16 part time employees. Thirty-three of our employees have Ph.D. or M.D. degrees and 99 of our employees are currently engaged in research and preclinical development activities. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be very strong.

In response to the COVID-19 pandemic, we implemented significant changes designed to ensure the safety and well-being of our employees as well as the communities in which we operate. We have not laid off any employees due to the pandemic. We implemented additional safety measures including masks and social distancing protocols in our offices and encouraged remote working arrangements for employees. To date, our remote working arrangements have not significantly affected our ability to maintain critical business operations.

**Corporate Information**

BiomX Ltd. is an Israeli company formed in March 2015 under the name "MBcure Ltd.", as an incubator company as part of the FutuRx incubator. In May 2017, the Company changed its name from MBcure Ltd. to BiomX Ltd.

BiomX Inc. was incorporated as a blank check company on November 1, 2017, under the laws of the State of Delaware, under the name "Chardan Healthcare Acquisition Corporation Inc.", for the purpose of entering into a merger, stock exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses or entities, which was referred to as a "target business." Efforts to identify a prospective target business were not limited to any particular industry or geographic location.

On December 18, 2018, we consummated our initial public offering or IPO of 7,000,000 units or Public Units. The Public Units sold in the IPO were sold at an offering price of $10.00 per Public Unit, generating total gross proceeds of $70,000,000. The Public Units each consist of one share of Common Stock or the Public Share and one warrant to purchase one-half of a share of Common Stock or the Public Warrant, with every two Public Warrants entitling the holder to purchase one share of Common Stock for $11.50 per full share.

Simultaneous with the consummation of the IPO, we consummated the private placement of an aggregate of 2,900,000 warrants or the Private Placement Warrants, each exercisable to purchase one share of Common Stock for $11.50 per share, to an affiliate of the Sponsor, at a price of $0.40 per Private Placement Warrant, generating total proceeds of $1,160,000.

On October 28, 2019, we and BiomX Ltd. consummated a business combination pursuant to a merger agreement dated as of July 16, 2019 and amended as of October 11, 2019, or the Merger Agreement, by and among the Company, BiomX Ltd., CHAC Merger Sub Ltd., an Israeli company and wholly owned subsidiary of the Company or the Merger Sub, and Shareholder Representative Services LLC, solely in its capacity as the shareholders' representative thereunder. Pursuant to the Merger Agreement, among other things, Merger Sub merged with and into BiomX Ltd., with BiomX Ltd. continuing as the surviving entity and a wholly owned subsidiary of the Company or the Business Combination. In connection with the Business Combination, the Company changed its name to BiomX Inc.

As of the October 28, 2019, all of the issued and outstanding shares and other equity interests in and of BiomX Ltd. immediately prior to the consummation of the Business Combination were canceled, and, in consideration therefor, the Company issued (or reserved for issuance) 16,625,000 shares of Common Stock or vested options or warrants to purchase Common Stock to BiomX Ltd. vested security holders.

In addition, we also agreed to issue the following number of additional shares of Common Stock, in the aggregate, to the BiomX Ltd. shareholders on a pro rata basis, subject to the Company's achievement of the conditions specified below following October 28, 2019:

a. 2,000,000 additional shares of the Company's Common Stock if the daily volume weighted average price of the Company's Common Stock in any 20 trading days within a 30-trading day period prior to January 1, 2022 is greater than or equal to $16.50 per share. This condition was not achieved and no shares were issued.

b. 2,000,000 additional shares of the Company's Common Stock if the daily volume weighted average price of the Company's Common Stock in any 20 trading days within a 30-trading day period prior to January 1, 2024 is greater than or equal to $22.75 per share.

c. 2,000,000 additional shares of the Company's Common Stock if the daily volume weighted average price of the Company's Common Stock in any 20 trading days within a 30-trading day period prior to January 1, 2026 is greater than or equal to $29.00 per share.

The mailing address of our principal executive office is 22 Einstein St., Floor 5, Ness Ziona, Israel 7414003 and the telephone number is (972) 72-394-2377. Our corporate website address is www.biomx.com. The content of our website is not intended to be incorporated by reference into this report or in any other report or document we file and any references to these websites are intended to be inactive textual references only.

**Information About Our Executive Officers**

The following table sets forth information regarding our executive officers as of the date of this Annual Report:

| Name | Age | Position |
|---|---|---|
| Jonathan Solomon | 45 | Chief Executive Officer and Director |
| Assaf Oron | 47 | Chief Business Officer |
| Dr. Merav Bassan | 56 | Chief Development Officer |
| Marina Wolfson | 38 | Senior Vice President of Finance and Operations |

*Jonathan Solomon* has served as the Chief Executive Officer and as a director of the Company since October 2019. Mr. Solomon served as Board member of BiomX Ltd. from February 2016 and also as Chief Executive Officer from February 2017 to October 2019. From July 2007 to December 2015, Mr. Solomon was a co-founder, President, and Chief Executive Officer of ProClara Biosciences Inc. (formerly NeuroPhage Pharmaceuticals Inc.), a biotechnology company pioneering an approach to treating neurodegenerative diseases. Prior to joining ProClara, he served for ten years in a classified military unit of the Israeli Defense Forces. Mr. Solomon holds B.Sc. magna cum laude in Physics and Mathematics from the Hebrew University, an M.Sc. summa cum laude in Electrical Engineering from Tel Aviv University, and an MBA with honors from the Harvard Business School.

*Assaf Oron* has served as the Chief Business Officer of the Company since October 2019. Mr. Oron served as Chief Business Officer of BiomX Ltd. from January 2017 to October 2019. Prior to this position, he served in various roles at Evogene Ltd. (Nasdaq:EVGN), an agriculture biotechnology company, which utilizes a proprietary integrated technology infrastructure to enhance seed traits underlying crop productivity, from March 2006 to December 2016, including Executive Vice President of Strategy and Business Development and Executive Vice President of Corporate Development. Prior to joining Evogene, Mr. Oron served as Chief Executive Officer of ChondroSite Ltd., a biotechnology company that develops engineered tissue products in the field of orthopedics and as a senior project manager and strategic consultant at Israeli management consulting company POC Ltd. Mr. Oron holds an M.Sc. in Biology (bioinformatics) and a B.Sc. in Chemistry and Economics, both from Tel Aviv University.

*Dr. Merav Bassan* has served as the Chief Development Officer of the Company since October 2019. Prior to this position, she served in various development roles at Teva Pharmaceutical Industries Limited between 2005 and 2019, including Vice President, Head of Translational Sciences, Specialty Clinical Development R&D from 2017 to 2019, Vice President, Pain and Global Internal Medicine, Project Leadership, Innovative Product Development, Global IR&D from 2015 to 2017, and Project Champion, Senior Director, Innovative Product Development, Global IR&D from 2009 to 2015. Dr. Bassan holds a B.Sc. in Biology, a M.Sc. in Human Genetics and a Ph.D. in Neurobiology from Tel Aviv University, and she completed a Post-Doctoral Fellowship in Neuroscience at Harvard Medical School at Harvard University.

*Marina Wolfson* has served as the Senior Vice President of Finance and Operations of the Company since October 2020. Ms. Wolfson served as the Vice President of Finance and Operations of the Company from December 2019 to October 2020. Ms. Wolfson's experience includes working with large pharmaceutical and hi-tech companies, as well as venture capital funds. Prior to joining the Company, Ms. Wolfson worked as Vice President of Finance at BioView Ltd. (TASE:BIOV) from 2010 to 2019 and a senior auditor at Ernst & Young, from 2007 to 2010. Ms. Wolfson is a certified public accountant in Israel and holds a B.A in Economics and Accounting (with honors) and an MBA (with honors, specializing in finance) from Ben-Gurion University.

## ITEM 1A. RISK FACTORS

*You should carefully consider the risks and uncertainties described below and the other information in this Annual Report before making an investment in our securities. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our securities could decline and you could lose all or part of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.*

### Risks Related to Our Business, Technology and Industry

***We are a clinical-stage company with limited operating history and have incurred losses since our inception. We anticipate that we will continue to incur significant expenses, and we will continue to incur significant losses for the foreseeable future.***

We are a clinical-stage biopharmaceutical company with limited operating history. We have incurred losses in each year since BiomX Ltd.'s inception in 2015. As of December 31, 2021, our accumulated deficit was $108.5 million, and we expect to incur increasingly significant losses for the foreseeable future. Preclinical development and clinical trials and activities are costly. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development and clinical trials for our product candidates. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term. For the years ended December 31, 2021 and 2020, we had losses from operations of $35.5 million and $30.3 million, respectively. We anticipate that the level of our expenses will continue to be significant if and as we:

- initiate and continue research, preclinical and clinical development efforts for any future product candidates;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek marketing and regulatory approvals for any product candidates that successfully complete clinical trials;
- require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization;
- maintain, expand and protect our intellectual property portfolio;
- expand our research and development infrastructure, including hiring and retaining additional personnel, such as clinical, quality control and scientific personnel;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize products for which we obtain marketing approval, if any; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization and help us comply with our obligations as a public company.

***We will need to raise additional capital in the future to support our operations which may not be available at terms that are favorable to us and might cause significant dilution to our stockholders or increase our debt towards third parties.***

As of December 31, 2021, we had cash, cash equivalents and restricted cash of $63.1 million, and we have had recurring losses from operations and negative operating cash flows since inception. We will need to raise additional capital in the future to support our operations and product development activities. In the near term, we expect to continue to fund our operations and other development activities relating to additional product candidates from the cash held by us, governmental and other grants and through future equity and debt financings. We have agreements with respect to additional tranches of our loan with Hercules Capital, Inc., or Hercules, and an additional equity investment by the CF Foundation, but each of these commitments is subject to us meeting future milestones, which may not occur. In connection with our efforts to raise additional capital, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on December 11, 2020. In addition, on December 4, 2020, we entered into an Open Market Sale Agreement[SM], or the Sale Agreement, with Jefferies LLC, or Jefferies, pursuant to which we may issue and sell shares of our Common Stock having an aggregate offering price of up to $50,000,000 from time to time through Jefferies. Through March 25, 2022, we sold an aggregate of 780,151 shares of Common Stock pursuant to the Sale Agreement for aggregate gross proceeds of $5,449,302. We may continue to sell shares under the Sale Agreement and otherwise to use our shelf registration statement to raise additional funds from time to time, as we did in July 2021. We may also raise funds privately, as we did in October 2021 in our agreements with a subsidiary of Maruho Co. Ltd., or Maruho, and in December 2021 with the CF Foundation. We may also seek funds through arrangements with collaborators or others that may require us to relinquish rights to the product candidates that we might otherwise seek to develop or commercialize independently. If we enter into a collaboration for one or more of our current or future product candidates at an earlier development stage, the terms of such a collaboration will likely be less favorable than if we were to enter the collaboration in later stages or if we commercialized the product independently. If we raise additional funds through equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights or cause significant dilution to our stockholders. If we raise additional capital through debt financing, it would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring or licensing intellectual property rights.

If we do not meet the milestones in our agreements with Hercules or the CF Foundation and/or additional capital is not available to us when needed or on acceptable terms, we may not be able to continue to operate our business pursuant to our business plan and may be required to delay our clinical development. While we believe that our existing cash and cash equivalents, together with our existing resources, will be sufficient to fund our planned operations until at least the end of 2023, we cannot provide assurances that our estimates are accurate, that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

Developing drugs and conducting clinical trials is expensive. Our future funding requirements will depend on many factors, including:

- the costs, timing and progress of our research and development and clinical activities;
- manufacturing costs associated with our targeted bacteriophage, or phage, therapies strategy and other research and development activities;
- the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish;
- employee-related expenses, as well as external costs such as fees paid to outside consultants;
- the costs and timing of seeking regulatory approvals and related to compliance with regulatory requirements; and
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights.

Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, or a bear market, or recession, ensues in the U.S. stock market, the Russian invasion of Ukraine and world sanctions on Russia, Belarus, and related parties and the impact associated with the COVID-19 pandemic, as well as geopolitical uncertainty and instability, such as the Russia-Ukraine conflict, our operating results and liquidity could be affected adversely by those factors in many ways, including making it more difficult for us to raise funds if necessary and our stock price may decline.

There can be no assurance that sufficient funds will be available to us when required or on acceptable terms, if at all. Our inability to obtain additional funds could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to a total loss of investment by our stockholders.

***The terms of our term loan agreement with Hercules place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

In August 2021, we entered into a term loan agreement, or the Hercules Loan Agreement, providing for a term loan in an aggregate principal amount of up to $30.0 million, subject to funding in three tranches and subject to certain terms and conditions. We received the first tranche of $15.0 million promptly after signing the agreement in August 2021. Two additional tranches in the amounts of $10 million and $5 million may become available to us to borrow upon the occurrence of certain milestone events. Our obligations under the Hercules Loan Agreement are secured by a lien on substantially all of our assets, other than intellectual property. We also agreed not to pledge or secure our intellectual property to others.

The Hercules Loan Agreement includes affirmative and negative covenants and events of default applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on our transferring collateral, making changes to the nature of our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, engaging in transactions with affiliates. Events of default include, among other things and subject to customary exceptions: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the Hercules Loan Agreement or other loan documents on a timely basis; (iii) failure to observe certain covenants under the loan and security agreement with Hercules; (v) occurrence of a material adverse effect; (vi) material misrepresentation by us; (vii) occurrence of any default under any other agreement involving material indebtedness; and (viii) certain material money judgments. If we default under the Hercules Loan Agreement, Hercules may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our Common Stock to receive any proceeds from the liquidation. Any declaration by Hercules of an event of default could significantly harm our business and prospects and could cause the price of our Common Stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***We are seeking to develop product candidates using phage technology, an approach for which it is difficult to predict the time and cost of development. To our knowledge, no bacteriophage has thus far been approved as a drug in the United States or in the European Union.***

We are developing our product candidates with phage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the FDA, or equivalent foreign regulatory agencies for a product based on this approach. While *in vitro* and *in vivo* studies have characterized the behavior of phage in cell cultures and animal models and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well-controlled modern clinical trials. Most of the prior research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II and lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, diminishing the relevance of prior claims of improved cure rates. Any product candidates that we develop may not demonstrate in patients the therapeutic properties ascribed to them in laboratory and other preclinical studies, and they may interact with human biological systems in unforeseen, ineffective or even harmful ways. We cannot be certain that our approach will lead to the development of approvable or marketable products. Furthermore, the bacterial targets of phage may develop resistance to our product candidates over time, which we may or may not be able to overcome with the development of new phage cocktails or we may not be able to construct a cocktail with sufficient coverage of our target pathogen universe.

If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenue sufficient to attain profitability. Our success will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates that we pursue as drugs, prescribing potential treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Our success will also depend on consumer acceptance and adoption of our products that we commercialize. Adverse events in preclinical studies and clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of phage therapeutics, could result in a decrease in demand for any product that we may develop. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage or reimbursement.

Developing our product candidates on a commercial scale will require substantial technical, financial and human resources. We and our third-party collaborators may experience delays in developing manufacturing capabilities for our product candidates, and may not be able to do so at the scale required to efficiently conduct the clinical trials required to obtain regulatory approval of those of our product candidates that require it, or to manufacture commercial quantities of our products, if approved or otherwise permitted to be marketed.

***Our product candidates must undergo clinical testing which may fail to demonstrate the requisite safety and efficacy for drug products, or safety, purity, and potency for biologics, and any of our product candidates could cause adverse effects, which would substantially delay or prevent regulatory approval and/or commercialization.***

Before we can obtain regulatory approval for a product candidate or otherwise obtain evidence allowing us to market the product as a drug or biologic, we must undertake extensive preclinical and clinical testing in humans to demonstrate safety and efficacy or in the case of biologics, safety, purity, and potency, to the satisfaction of the FDA or other regulatory agencies. Clinical trials of product candidates sufficient to obtain regulatory marketing approval or otherwise demonstrate safety prior to marketing, are expensive and take years to complete, especially for our product candidate designed to treat CRC as the phage will be genetically modified, which could make the conduct of clinical trials more complex and subject such trials to additional regulatory oversight. Furthermore, results from these clinical trials may not show safety or efficacy of our product candidates sufficient to lead to approval, or to warrant further development. For example, in October 2021, we announced the results of a Phase 2 cosmetic clinical study of our BX001 product candidate that showed no meaningful difference for efficacy relative to the placebo arm of the study, and therefore decided not to continue pursuing this program despite the time and expenses that had been incurred to date in its development. Our approach is intended to design phage combinations, or cocktails, to target specific strains of pathogenic bacteria in order to alter microbiome composition and confer potential therapeutic or cosmetic benefit to patients. However, there can be no assurance that the eradication of the selected targets will result in a clinically meaningful effect on the underlying disease, such as in cases where the pathology of the disease is not well-defined. In addition, the bacteria that we target may be associated with the disease, but may not be causative or contributive to the pathology of the disease, or there may be other bacteria that our product candidates do not target that are more meaningful drivers of the underlying disease. In addition, our product candidates require the use of effective delivery vehicles to reach the target organ or tissue, and there can be no assurance that our intended delivery systems will allow our product candidates to reach the desired locations in a patient. Safety must first be established through preclinical testing and early clinical trials, before efficacy can be evaluated and established and thereby lead to FDA or other regulatory agencies marketing approval. Our clinical trials may produce undesirable side effects or negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs.

***The ongoing COVID-19 pandemic and other geopolitical instability have and may continue to adversely affect our business, including our clinical trials.***

The COVID-19 pandemic has had and continues to have a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we temporarily had closed our executive offices with our administrative employees continuing their work outside of our offices and may need to close them again in the future. In addition, general economic, political, demographic and business conditions worldwide, including geopolitical uncertainty and instability, such as the Russia-Ukraine conflict, might adversely affect our business, through indirect disruption to our supply chain, harming our ability to raise funds at terms acceptable to us among other affects. Also, due to the COVID-19 pandemic we have modified our business practices, including restricting employee travel, developing social distancing plans for our employees and cancelling physical participation in meetings, events and conferences. As a result of the COVID-19 pandemic, we have experienced and may continue to experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, in the U.S. and the government in Israel, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruptions or delays to our sourced discovery and clinical activities.

The pandemic and the resulting government actions have impacted and may continue to adversely impact our planned and ongoing clinical trials. Clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients have not been willing and/or able to comply with clinical trial protocols due to the COVID-19 pandemic, particularly if quarantines or other restrictions impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 has been impeded and may continue to remain impeded, which would adversely impact our clinical trial operations. The diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators and hospitals serving as our clinical trial sites, may significantly disrupt our research activities. As a result, the expected timeline for data readouts of our clinical trials and certain regulatory filings will likely be negatively impacted, which would adversely affect and delay our ability to obtain regulatory approvals for our product candidates, increase our operating expenses and have a material adverse effect on our financial condition.

Furthermore, the response to the COVID-19 pandemic may redirect resources with respect to regulatory matters and intellectual property matters in a way that would adversely impact our ability to progress regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions. Comparable regulatory authorities in other jurisdictions may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and provide guidance regarding the conduct of clinical trials. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The COVID-19 pandemic continues to evolve. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States Canada, Europe, Israel and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, Canada, Europe, Israel and other countries to contain and treat the disease. As a result, the COVID-19 pandemic may have a material adverse effect on our business, results of operations, financial condition and prospects and heighten many of our known risks described or referenced in this “Risk Factors” section.

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates for therapeutic indications, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our future ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization for therapeutic indications, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to regulation by the FDA and other regulatory agencies in the United States and by equivalent foreign regulatory authorities. Before we can commercialize any of our product candidates for therapeutic indications, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

The process of obtaining regulatory approvals for therapeutic indications, both in the United States and in other countries, is expensive, may take many years if additional clinical trials are required, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and equivalent foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or equivalent foreign regulatory authorities may disagree with the design, including study population, dose level, dose regimen, and bioanalytical assay methods, or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or equivalent foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or equivalent foreign regulatory authorities for approval, such as was the case with our acne product candidate;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or equivalent foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a marketing application or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or equivalent foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or equivalent foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or equivalent foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market its product candidates, which would significantly harm our business, results of operations and prospects.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval for therapeutic indications. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials. In the European Union, the safety and efficacy data of our product candidate for the treatment of CRC will be reviewed by the European Medicines Agency's, or the EMA's, Committee for Advanced Therapies, or CAT, a group of experts in advanced therapy medicinal products. Our other product candidates would be reviewed by CAT as well if the EMA were to consider that they also qualify as advanced therapy medicinal products.

Moreover, under PREA, in the United States, and the Pediatric Regulation, in the European Union, the FDA or equivalent foreign regulatory authority could require mandatory testing in the pediatric population. Applications for approval in the United States or in the European Union must contain data to assess the safety and efficacy of the biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA or equivalent foreign regulatory authority may, in its discretion, grant full or partial waivers, or deferrals, for submission of data in pediatric subjects. If the FDA requires data in pediatric patients, significantly more capital will have to be invested in order to conduct the mandatory pediatric clinical trials and studies, but the approval of the medicinal products for the adult population should normally not be affected. If the results of such pediatric studies are not positive, our product candidates will not be approved for children.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited therapeutic indications than our requests, may include limitations for use or contraindications that limit the suitable patient population, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our future ability to generate revenues will be materially impaired.

***We have never generated any revenue from product sales and may never be profitable or, if achieved, may not sustain profitability.***

Our ability to generate meaningful revenue and achieve profitability depends on our ability, and the ability of any third party with which we may partner, to successfully complete the development of, and meet regulatory requirements, including (but not limited to) obtaining any necessary regulatory approvals, to commercialize our product candidates. We do not currently meet regulatory requirements or have the required approvals to market our product candidates and may never meet or receive them. We do not anticipate generating revenue from product sales for the foreseeable future, if ever. If any of our product candidates fail in clinical trials or if any of our product candidates do not meet regulatory requirements, including gaining regulatory approval when needed, or if any of our product candidates, if marketed, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenue from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials;
- meeting regulatory requirements for marketing the products;
- developing a sustainable, scalable, reproducible and transferable manufacturing process for our product candidates;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval or are otherwise permitted to market, either by establishing a sales force, marketing and distribution infrastructure or by collaborating with a partner;
- obtaining market acceptance of any approved products;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- identifying and validating new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale or otherwise permitted for marketing, we anticipate incurring significant costs associated with commercializing any approved product. Our expenses could increase beyond expectations if we are required by the FDA, or the EMA, or other equivalent foreign regulatory agencies to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable, or if we are unable to fund our continuing losses, our business, financial condition and results of operations may be materially adversely impacted.

***We are seeking to develop product candidates to treat medical conditions related to the presence of certain bacteria. Our success is largely dependent on a broad degree of market acceptance, and in the case of drug products, physician adoption and use, which are necessary for commercial success.***

Even if we obtain FDA or foreign regulatory approvals for our drug product candidates, the commercial success of our product candidates will depend on consumer acceptance and adoption of products that we commercialize. Adverse events in preclinical studies and clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity could result in a decrease in demand for any product that we may develop.

In addition, the commercial success of our drug product candidates will depend significantly on their broad adoption and use by pediatricians and other physicians for approved therapeutic indications, as well as any other indications for which we may seek approval. We cannot be certain that our approach will lead to the development of approvable or marketable products.

***Obtaining high titers for specific phage cocktails necessary for our preclinical and clinical testing may be difficult and time-consuming.***

Our product candidates are phage cocktails that we have designed to meet specific characteristics. We and our contract manufacturers produce a cocktail of multiple phage and it may be difficult or time-consuming to achieve high titers, or levels, of phage sufficient for our preclinical and clinical testing. In some cases, it may require multiple product runs in order for us to obtain the amounts necessary for its clinical testing. This may result in delays in our clinical trial timelines, and it may increase production costs and associated expenses. Also, it may be difficult to reproduce the manufacturing process to the extent that more significant quantities are required as our product candidates advance through the clinical development process.

***Results from preclinical studies of our product candidates may not be predictive of the results of clinical trials or later stage clinical development.***

Preclinical studies of our product candidates, such as BX003, including studies in animal disease models in the case of BX003 and other studies, may not accurately predict the safety of the product candidate such that further human clinical trials would be allowed to proceed. In particular, promising preclinical testing suggesting the potential efficacy of prototype phage products may not predict the ability of these products to address conditions in the human clinical settings. For example, while we have studied phage activity *in vitro* and *in vivo*, in the case of BX003, these results may not be replicated when our phage cocktails are administered to human subjects. Despite promising data in any preclinical studies, our phage technology may be found not to be efficacious when studied in clinical trials.

To satisfy FDA or equivalent foreign regulatory approval standards, we must demonstrate in adequate and well controlled clinical trials that our drug product candidates are safe and effective for their intended use. Success in preclinical testing and early-stage clinical trials does not ensure that later clinical trials will be successful. Our initial results from preclinical testing also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials, and most product candidates that commence clinical trials are never approved for commercial sale.

***Our product candidates are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates.***

Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our drug product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. To satisfy FDA or equivalent foreign regulatory approval standards, we must demonstrate in adequate and well controlled clinical trials that our drug product candidates are safe and effective for their intended use. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Given the uncertainties around phage therapy, our product candidates could require a significantly longer time to gain regulatory approval than expected or may never gain approval. This is especially so for the product candidate designed to treat CRC as the phage will be genetically modified, which adds potential complexity to the process, particularly in the European Union. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenue and to achieve profitability.

Regulatory requirements for development of our product candidates are uncertain and evolving. Changes in these laws or the current interpretation or application of these laws would have a significant adverse impact on our ability to develop and commercialize our product candidates. The legal and regulatory status of phage therapy remains unclear in many countries, including the European Union. Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, or changes in regulatory review practices for a submitted product application may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval.

Regulatory approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product, as well as the approved labeling for the product. These limitations could adversely affect our potential product revenue. Regulatory approval may also be conditioned on costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, our manufacturer and our manufacturing facilities will be subject to registration and listing requirements and continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions and criminal prosecution.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

- the therapeutic endpoints chosen for evaluation;
- the eligibility criteria defined in the protocol;
- the perceived benefit of the product candidate under study;

- the size of the patient population required for analysis of the clinical trial's therapeutic endpoints;
- our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- competition for patients from clinical trials for other treatments.

We have experienced and may continue to experience difficulties in enrolling patients in our clinical trials, including due to the impacts of COVID-19, which could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations. In addition, potential patients for our trials may not be adequately diagnosed or identified with the diseases that we are targeting or may not meet the entry criteria for our studies.

We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or equivalent foreign regulatory agencies. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials.

***Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delays in our ability to obtain regulatory approval for and commercialization of our product candidates.***

Delays in our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our product candidates. Planned clinical trials may not be commenced or completed on schedule, or at all.

Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophage in sufficient quantities to support our clinical trials;
- the availability of financial resources to commence and complete our planned clinical trials;
- delays in reaching a consensus with clinical investigators on study design;
- delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials;
- regulatory constraints or injunctions (for example, from supervisory authorities in case of noncompliance with cybersecurity and data privacy laws);
- failure by clinical trial sites, other third parties or us to adhere to clinical trial agreements and/or the trial protocol;
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining IRB or independent ethics committee approval; and
- adverse safety events experienced during our clinical trials.

If we do not successfully commence or complete our clinical trials on schedule, the price of our securities may decline. Significant preclinical or clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

***Our current or future product candidates may cause adverse effects that could halt their clinical development, prevent their approval or marketing, limit their commercial potential or result in significant negative consequences.***

Adverse effects could occur and cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or equivalent foreign regulatory agencies. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If adverse effects arise in the development of our product candidates, we, the FDA or equivalent foreign regulatory agencies, the IRBs or independent ethics committees at the institutions in which our studies are conducted, or the Data Safety Monitoring Board could suspend or terminate our clinical trials or the FDA or equivalent foreign regulatory agencies could deny approval of our product candidates for any or all targeted indications.

We intend to continue to evaluate our product candidates for safety and tolerability in the form of Phase 1 clinical trials. While our current and future product candidates will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Unforeseen adverse effects could arise either during clinical development or, if such adverse effects are more rare, after our products have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. For example, while we screen our phage in attempts to minimize safety issues, there can be no assurance that we will eliminate the risk of the appearance of virulence genes, antibiotic resistance genes, lysogenic genes, integrase genes, or other toxic genes in our phage, or of adverse reactions to our phage in a patient's immune system. So far, we have not demonstrated, and we cannot predict, if ongoing or future clinical trials will demonstrate that any of our product candidates are safe in humans. Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable adverse effects.

Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials. Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase commercialization costs.

***We have not completed composition development of our product candidates.***

The development of our product candidates requires that we isolate, select, optimize and combine a number of phage that target the desired bacteria for that product candidate. The selection of phage for any of our product candidates is based on a variety of factors, including, without limitation, the ability of the selected phage, in combination, to successfully kill the targeted bacteria, the degree of cross-reactivity of the individual phage with the same part of the bacterial targets, the ability of the combined phage to satisfy regulatory requirements, our ability to manufacture sufficient quantities of the phage, intellectual property rights of third parties, and other factors. While we have selected an initial formulation of BX003, there can be no assurance that this initial formulation will be the final formulations of this product candidate for commercialization if approved. If we are unable to complete formulation development of our product candidates in the time frame that we have anticipated, then our product development timelines, and the regulatory approval of our product candidates, could be delayed.

***We must continue to develop manufacturing processes for our product candidates, and any delay in doing so, or our inability to do so, would result in delays in our clinical trials.***

The manufacturing processes for our product candidates, and the scale-up of such processes for clinical trials, may present challenges, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. Any delay in the development or scale-up of these manufacturing processes could delay the start of clinical trials and harm our business. In order to scale-up our manufacturing capacity, we need to either build additional internal manufacturing capacity, contract with one or more partners, or both. Our technology and the production process for our equipment and tools are complex and we may encounter unexpected difficulties in manufacturing our product candidates. For example, the manufacturing hosts that we use to produce our phage may contain one or more integrated phage in their genomes that, if we are unable to remove, can present challenges in manufacturing of the produced phage. There is no assurance that we will be able to continue to build manufacturing capacity internally or find one or more suitable partners, or both, to meet the necessary volume and quality requirements. Manufacturing and product quality issues may arise as we increase the scale of our production. Any delay or inability in establishing or expanding our manufacturing capacity could diminish our ability to develop our product candidates.

In the third quarter of 2019, we established our own manufacturing facility at our headquarters in Ness Ziona, Israel and we have executed cGMP manufacturing for our first in human clinical study (IBD project). In March 2021, we moved into a new manufacturing facility at our headquarters in Ness Ziona, Israel. Our new facility undergoes ongoing internal inspections to verify proper manufacturing for Phase I and II clinical studies in accordance with cGMP requirements. In the event this facility does not comply with cGMP standards for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate.

If we submit marketing applications for any of our product candidates manufactured at this facility, this manufacturing facility will be subjected to ongoing periodic inspection for compliance with European, FDA and cGMP regulations. Compliance with these regulations and standards is complex and costly, and there can be no assurance that we will be able to comply. Any failure to comply with applicable regulations could result in sanctions being imposed (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecution.

***If our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited.***

Competition in the biotechnology and pharmaceutical industries is intense and continues to increase. Some companies that are larger and have significantly more resources than us are aggressively pursuing development programs for indications that we are pursuing, including traditional therapies and therapies with novel mechanisms of action. In addition, other companies are developing phage-based products for therapeutic and non-therapeutic uses, and may elect to use their expertise in phage development and manufacturing to try to develop products that would compete with our products.

We also face potential competition from academic institutions, government agencies and private and public research institutions engaged in the discovery and development of drugs and therapies. Many of our competitors have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing, sales and marketing than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies.

In the European Union, potential competition also comes from medicinal preparations made by hospitals or pharmacists and administered without marketing authorizations, generally referred to as “compounding.” In some member states, national authorities generally promote compounding in order to reduce healthcare expenses.

Our competitors may succeed in developing products that are more effective, have fewer side effects and are safer or more affordable than our product candidates, which would render our product candidates less competitive or noncompetitive and would prevent the granting or maintenance of an orphan designation. These competitors also compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as to acquire technology and technology licenses complementary to our programs or advantageous to our business. Moreover, competitors that are able to achieve patent protection, obtain regulatory approvals and commence commercial sales of their products before we do, and competitors that have already done so may enjoy a significant competitive advantage.

***We may not be successful in our efforts to identify or discover additional product candidates.***

Although we intend to utilize our technology to evaluate other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify other product candidates for clinical development for a number of reasons. For example, our research methodology may not be successful in identifying potential product candidates, or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. In addition, we may not be able to identify phage that eradicate the target bacteria, including due to sourcing difficulties such as lack of diversity, inability to obtain samples in a timely manner or at all, or contamination in the samples. We may also encounter difficulties in designing phage cocktails that meet the requirements of an investigational therapy, including due to the build-up of resistances in bacteria to our phage, the range of host bacteria that are affected by our phage, the variety of activity on different bacteria growth states, issues with toxicity in our phage, and the stability, robustness and ease of manufacturing of our product candidates. In addition, the designing of synthetically engineered phage may fail to result in the development of phage with the desired characteristics or behaviors that are suitable for use as viable therapies, or may result in phage that contain undesired features such as immunogenicity, toxicity and other safety concerns.

A key part of our strategy is to utilize our screening technology to identify product candidates to pursue in clinical development. If we fail to identify and develop additional potential product candidates, we may be unable to grow our business and our results of operations could be materially harmed. Such product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory agencies. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development.

***Legal requirements as well as ethical and social concerns about synthetic biology and genetic engineering could limit or prevent the use of our technologies and limit our revenues.***

Our technology may include the use of synthetic biology and genetic engineering. In some countries, drugs made using genetically modified organisms may be subject to a more stringent legal regime, which could prove to be complex and very challenging, especially for a small life sciences company. For example, in the European Union, the rules on genetically modified organisms would apply in addition to the general rules on medicinal products or cosmetic products. The rules on advanced therapy medicinal products may also apply.

Additionally, public perception about the safety and environmental hazards of, and ethical concerns over, synthetic biology and genetic engineering could influence public acceptance of our technologies, product candidates and processes. If we and our collaborators are not able to overcome the legal challenges as well as the ethical and social concerns relating to synthetic biology and genetic engineering, our technologies, product candidates and processes may not be accepted. These challenges and concerns could result in increased expenses, regulatory scrutiny and increased regulation, trade restrictions on imports of our product candidates, delays or other impediments to our programs or the public acceptance and commercialization of our products. We design and produce product candidates with characteristics comparable or superior to those found in naturally occurring organisms or enzymes in a controlled laboratory; however, the release of such organisms into uncontrolled environments could have unintended consequences. Any adverse effect resulting from such a release could have a material adverse effect on our business, financial condition or results of operations, and we may have exposure to liability for any resulting harm.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. For example, we spent significant time and resources developing our BX001 product candidate, which we have now discontinued.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

***We intend to rely on our new BOLT (BacteriOphage Lead to Treatment) proprietary product platform to develop our phage therapies. Our competitive position could be materially harmed if our competitors develop similar platforms and develop rival product candidates.***

Our new BOLT platform enables us to rapidly develop, manufacture and formulate phage therapy candidates targeting particular pathogenic bacteria and incorporates our experience over the past six years with process refinement and implementation of technological advancements. For a given indication, the platform will allow for the completion of a clinical proof of concept study in patients, meaning Phase 2 results, within approximately 12-18 months from project initiation; however in certain indications the length of clinical proof of concept may be longer depending on the indication, identity of target bacteria, recruitment rate, cohort size and other factors, and we may not achieve clinical proof of concept on that timeline, or at all. We are initially aiming to complete a clinical proof of concept study in patients within approximately 12-18 months from project initiation in our cystic fibrosis and atopic dermatitis programs. Our BOLT platform is new and may not achieve the benefits we anticipate. To the extent we utilize our resources to further develop our BOLT platform, we may become more dependent on its success.

***There is a substantial risk of product liability claims in our business. If we do not obtain sufficient liability insurance, a product liability claim could result in substantial liabilities to us.***

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or failure to complete our clinical trials;
- withdrawal of clinical trial participants;
- decreased demand for our product candidates;
- injury to our reputation;
- litigation costs;
- substantial monetary awards against us; and
- diversion of management or other resources from key aspects of our operations.

If we succeed in marketing products, product liability claims could result in an FDA or equivalent foreign regulatory agency investigation of the safety or efficacy of our products, our manufacturing processes and facilities or our marketing programs. Such investigation could also potentially lead to a recall of our products or more serious enforcement actions, or limitations on the indications, for which they may be used, or suspension or withdrawal of approval.

We currently only have limited clinical trials insurance policies that cover clinical trials in certain territories. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates or any other compound that we may develop. However, insurance coverage is expensive, and we may not be able to maintain insurance coverage at a reasonable cost or at all, and the insurance coverage that we have or obtain may not be adequate to cover potential claims or losses.

***Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

***The FDA and other equivalent foreign regulatory agencies may implement additional regulations or restrictions on the development and commercialization of products which act on the microbiome, which may be difficult to predict.***

The FDA and equivalent foreign regulatory agencies in other countries have each expressed interest in further regulating biotechnology products and product candidates, such as those that act on the human microbiome. Agencies at both the federal and state level in the United States, as well as the U.S. congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in non-IND human clinical studies or clinical trials of microbiome products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner if at all.

***Exchange rate fluctuations between the U.S. Dollar, the New Israeli Shekel, the Euro and other foreign currencies, may negatively affect our future expenses.***

Our proceeds from sales of our securities are generally received in U.S. Dollars. Our headquarters are located in Israel, where the majority of our general and administrative expenses and research and development costs are incurred in the New Israeli Shekel, or NIS. Future expenses may be incurred in foreign currencies such as the Euro or British Pound. As a result, our financial results may be affected by fluctuations in the exchange rates of currencies in the countries. For example, during 2020, we witnessed a strengthening of the average exchange rate of the NIS against the U.S. Dollar, which increased the U.S. Dollar value of Israeli expenses. If the NIS strengthens against the U.S. Dollar, as it did in 2020 and 2021, the U.S. Dollar value of our Israeli expenses, mainly personnel and facility-related, will increase. We use foreign exchange contracts (mainly option and forward contracts) to hedge balance sheet items from currency exposure. However, these foreign exchange contracts are not designated as hedging instruments for accounting purposes and they may not be effective. Although exposure to currency fluctuations to date has not had a material adverse effect on our business, there can be no assurance that fluctuations in the future will not have a material adverse effect on our operating results and financial condition.

***Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.***

Since inception in 2015, BiomX Ltd. has devoted substantially all of its resources to developing product candidates with phage technology through its preclinical programs, building its intellectual property portfolio, developing a supply chain, planning its business, raising capital and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully complete any clinical study or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as an early-stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our product candidates, we will need to transition from a company with a research focus to a company capable of supporting clinical development and, if successful, commercial activities. We may not be successful in such a transition.

***We need to grow the size of our organization and may experience difficulties in managing this growth.***

As our research, development, manufacturing and commercialization plans and strategies develop as a public company, we need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, compensating, integrating, maintaining and motivating additional employees;
- managing our internal research and development efforts effectively, including identification of clinical candidates, scaling our manufacturing process and navigating the clinical and FDA review process for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***We are an "emerging growth company," and we cannot be certain that the reduced disclosure requirements applicable to "emerging growth companies" will not make our Common Stock less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we intend to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, compliance with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Further, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will remain an emerging growth company until the earliest of (a) the last day of our fiscal year during which we have generated total annual gross revenue of at least $1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of our IPO; (c) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act.

**Risks Related to Government Regulation**

***Breakthrough Therapy Designation or Fast Track Designation by the FDA, even if granted for any of our product candidates developed for therapeutic indications, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.***

In the United States, we may seek a Breakthrough Therapy Designation for some of our product candidates, including BX003 or our cystic fibrosis product candidate under development. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Breakthrough designation also provides sponsors with the potential for rolling review of a BLA. Designation as a breakthrough therapy is within the discretion of the FDA.

In the European Union, the PRIME (PRIority MEdicines) status is similar to the Breakthrough Therapy Designation. The EMA has implemented the PRIME status to support the development and accelerate the approval of complex, innovative medicinal products addressing an unmet medical need. The PRIME status enables early dialogue with the relevant EMA scientific committees and, possibly, some payors and thus reinforces the EMA's scientific and regulatory support. The PRIME status, which is granted at the EMA's discretion, focuses on medicinal products the marketing authorization of which qualifies for accelerated assessment (medicinal products of major interest from a public health perspective, in particular from a therapeutic innovation perspective).

Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy or for PRIME status, the FDA or EMA, respectively, may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation or PRIME status for a product candidate may not actually result in a faster development process, review or approval compared to therapies considered for approval under conventional procedures and does not assure ultimate approval. In addition, even if one or more of our product candidates qualify as breakthrough therapies or is granted PRIME status, the FDA or EMA, respectively, may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened.

In the United States, we may seek Fast Track Designation for some of our product candidates for therapeutic indications. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation; we cannot assure you that the FDA would decide to grant it. Even if we receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if we believe that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

Other countries may have adopted schemes designed to ensure an accelerated approval of drugs that are especially important for patients. For example, in the European Union, the EMA may agree to an accelerated assessment (150 days instead of 210 days) for medicinal products of major interest from a public health perspective, in particular from a therapeutic innovation perspective). Furthermore, competent regulatory authorities may grant market authorizations "under exceptional circumstances," in cases where all the required safety and efficacy data have not been and will not be collected, to medicinal products designed for unmet needs or orphan medicinal products. Although a marketing authorization under exceptional circumstances is definitive, the risk-benefit balance of the medicinal product must be reviewed annually and the marketing authorization is withdrawn if it becomes negative. Moreover, under the centralized procedure, the European Commission may grant "conditional marketing authorizations" in cases where all the required safety and efficacy data are not yet available. The conditional marketing authorization is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. If the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization ceases to be renewed. As with Fast Track Designation, the competent regulatory authorities in the European Union have broad discretion whether or not to grant such an accelerated assessment or approval and, even if such assessment or approval is granted, we may not experience a faster development process, review or approval compared to conventional procedures.

***We may fail to obtain and maintain orphan drug designations from the FDA or equivalent foreign regulatory agencies for our current and future therapeutic product candidates, as applicable.***

In the United States, under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, the orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has the orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective, or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek the orphan drug designation for our product candidates, we may never receive such designation.

An orphan drug legal regime also exists in the European Union. The EMA's Committee for Orphan Medicinal Products, or COMP, gives opinions, and the European Commission takes decisions, on the granting of the orphan drug designation to the development of products that are intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Economic Area (European Union plus Iceland, Liechtenstein and Norway); or (ii) a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Economic Area would be sufficient to justify the necessary investment in developing the drug or biological product. The granting of the orphan designation requires that there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, that the future medicine is to be of significant benefit to those affected by the condition. The test for that later condition is stringent, because the future product must be compared with all existing therapies for the rare condition, including surgical operations, already authorized medicinal products and compounded preparations (subject to certain conditions). At the time of marketing authorization, the orphan designation is reviewed again by the COMP in view of the maintenance of the orphan status. If the designation criteria are no longer met, the European Commission withdraws the orphan designation. Maintenance of the orphan designation at the time of marketing authorization means that all the drugs/biologicals authorized since the granting of the designation become relevant for determining the lack of satisfactory therapy or the significant benefit.

If obtained, the orphan drug designation would entitle us to financial incentives, such as reductions of fees or fee waivers and 10 years of market exclusivity. Market exclusivity precludes the EMA or the national competent authorities from validating a marketing authorization application, and the European Commission or a national competent authority from granting a marketing authorization, for a same or similar drug/biological and the same therapeutic indication. The 10-year period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is not sufficiently profitable to justify maintenance of market exclusivity. The orphan exclusivity may also be lost vis-à-vis another drug/biological in cases where the manufacturer is unable to assure sufficient quantity of the drug to meet patient needs or if that other product is proved to be clinically superior to the approved orphan product. A drug/biological is clinically superior if it is safer, more effective or makes a major contribution to patient care.

***Even if we receive regulatory approval of any product candidates for therapeutic indications, we will be subject to ongoing regulatory compliance obligations and continued regulatory review, which may result in significant additional expense. Additionally, any of our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

If any of our product candidates is approved for therapeutic indications, we will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, advertising, promotion, sampling, recordkeeping, export, import, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of equivalent foreign regulatory agencies. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and equivalent foreign regulatory agency requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing applications and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The FDA or equivalent foreign regulatory agencies have significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA or equivalent foreign regulatory agencies may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or an equivalent foreign regulatory agency approves our product candidates, we will have to comply with requirements, including submissions of safety and other post-marketing information and reports and registration.

The FDA or equivalent foreign regulatory agencies may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements may result in revisions to the approved labeling to add new safety information, the imposition of post-market studies or clinical trials to assess new safety risks, or the imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of products from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled enforcement letters, or holds on clinical trials;
- refusal by the FDA or equivalent foreign regulatory agencies to approve pending applications or supplements to approved applications filed by us or the suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA or equivalent foreign regulatory agencies strictly regulate the marketing, labeling, advertising and promotion of drug products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label or other regulatory marketing pathway. The FDA and equivalent foreign regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA or equivalent foreign regulatory agencies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and the ability to achieve or sustain profitability.

The policies of the FDA or equivalent foreign regulatory agencies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

Noncompliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance requirements, can also result in significant financial penalties.

***We may conduct clinical trials for our product candidates outside the United States, and the FDA may not accept data from such trials.***

We have and may continue to conduct certain clinical trials or a portion of our clinical trials for our product candidates outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

***Any products that we may develop may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could make it difficult for us to sell any product candidates or therapies profitably.***

The regulations that govern pricing for new medical products vary widely from country to country. As a result, we might obtain regulatory approval for a product in a particular country but then be subject to pricing regulations in that country that delay the commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. In addition, our ability to commercialize any approved products successfully will depend in part on the extent to which reimbursement for these products will be available from government health administration authorities, private health insurers and other organizations. Even if we succeed in bringing one or more therapeutic products to market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell them on a competitive basis. If the price we are able to charge for therapeutic products is inadequate in light of our development and other costs, our future profitability could be adversely affected.

***Ongoing health care legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.***

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products, or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain health care costs. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers and significantly impacted the United States pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; and extended the rebate program to individuals enrolled in Medicaid managed care organizations. It also established annual fees and taxes on manufacturers of certain branded prescription drugs and creates a new Medicare Part D coverage gap discount program in which manufacturers must now agree to offer 50% point of sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024. It is unclear how other healthcare reform measures of the Biden administration, if any, will impact our business.

These laws and future state and federal health care reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

A similar movement is observed in the European Union countries. Criteria for pricing and reimbursement, which vary from country to country, are regularly amended and tightened in order to reduce the draw on the budget allocated to national health insurance systems. Moreover, the system of reference pricing (the price in a country calculated on the basis of prices in other countries with typically lower prices) leads to price reductions in countries that traditionally granted high prices.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary regulatory authorities, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. On February 7, 2022, the FDA announced that domestic inspections across all commodities will resume due to the decline in COVID-19 cases in the U.S. Previously planned foreign surveillance inspections that have received country clearance and are within the Centers for Disease Control and Prevention's Level 1 or Level 2 COVID-19 travel recommendation will also proceed. Planning for additional foreign surveillance inspections is ongoing, with an anticipated goal of conducting foreign prioritized inspections starting in April 2022. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***We are subject to certain U.S. and foreign anticorruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.***

Among other matters, U.S. and foreign anticorruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

**Risks Related to our Licensed and Co-Owned Intellectual Property**

***The license agreements we maintain, including the Yeda 2015 License Agreement, with Yeda are important to our business. If we or the other parties to our license agreements fail to adequately perform under the license agreements, or if we or they terminate the license agreements, the development, testing, manufacture, production and sale of our phage-based therapeutic product candidates would be delayed or terminated, and our business would be adversely affected.***

The Yeda 2015 License Agreement provides for an exclusive worldwide license to certain know-how and research information related to the development, testing, manufacture, production and sale of microbiome-based therapeutic product candidates, including candidates specified in the agreement, which are used in our phage discovery platform, as well as patents, research and other rights to phage product candidates resulting from the work of the consultants identified in the agreement and further research that we funded. The License Agreement terminates upon the later of the expiration of the last of the patents covered under the License Agreement and the expiry of a continuous 15-year period during which there has not been a first commercial sale of any product in any country. Yeda may also terminate the agreement if we fail to observe certain diligence and development requirements and milestones as described in the License Agreement. we or Yeda may terminate the agreement for the material uncured breach of the other party after a notice period or the other party's winding up, bankruptcy, insolvency, dissolution or other similar discontinuation of business. Upon termination of the agreement, other than due to the passage of time, we are required to grant to Yeda a nonexclusive, irrevocable, perpetual, fully paid-up, sublicensable, worldwide license in respect of our rights in know-how and research results as described in the Yeda 2015 License Agreement, provided that, if Yeda subsequently grants a license to a third party that utilizes our rights, we are entitled to share in the net proceeds actually received by Yeda arising out of that license, subject to a cap based on the development expenses that we incur in connection with the License Agreement. For more information on the License Agreement, see "*Business—Material Agreements—License Agreements—License Agreement with Yeda.*"

We also maintain additional license agreements:

- with Keio and JSR, pursuant to which we were granted an exclusive, royalty-bearing, worldwide, perpetual sublicense by JSR to certain patent rights related to our IBD program. Specifically, these patent rights relate to bacterial targets that have been observed to be related to IBD and the phage that were observed to eradicate these bacterial targets; and

- with Keio and JSR, pursuant to which we were granted an exclusive, royalty-bearing, worldwide, perpetual sublicense by JSR to certain patent rights related to PSC program. Specifically, these patent rights relate to bacterial targets that have been observed to be related to PSC and the phage that were observed to eradicate these bacterial targets.

Termination of the license agreements could cause significant delays in our product and commercialization efforts that could prevent us from commercializing our product candidates, including our microbiome-based therapeutic product candidates, without first expanding our internal capabilities or entering into other agreements with third parties. Any alternative collaboration or license could also be on less favorable terms to us.

***We are highly dependent on intellectual property licensed from third parties, and termination or limitation of any of these licenses could result in the loss of significant rights and materially harm our business.***

We currently rely on licenses from third-party collaborators for certain aspects of our technology and for certain of our existing programs. In particular, we received exclusive, royalty-bearing licenses to certain patents held by third parties, including Yeda, Keio and JSR. Our license agreement with Yeda provide license to certain know-how and research information related to the development, testing, manufacture, production and sale of microbiome-based therapeutic product candidates that are used in our phage discovery platform, as well as patents, research and other rights to phage product candidates resulting from the work of the consultants identified in the agreement and further research that we funded. Our license agreements with Keio and JSR provide licenses to patents related to, among other things, IBD and PSC programs. Pursuant to these license agreements, we are required to pay annual license fees, as well as a contingent consideration comprised of milestone and royalty payments, which depend on the achievement of future milestones and potential revenue from products.

If we fail to comply with our obligations under our license agreements, including payment terms, our licensors may have the right to terminate our license agreements, in which event we may not be able to develop, manufacture, market or sell the products covered by those license agreements. We may also face other penalties under our license agreements if we do not meet our contractual obligations. Such an occurrence could materially adversely affect the value of our products being developed under any such license agreements. Termination of one or more of our license agreements, or reduction or elimination of our rights under these license agreements, may result in us having to negotiate new or reinstated license agreements, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to commercialize the affected product candidates.

In the future, we may rely upon additional licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates and proprietary product platform. Patent rights that we in-license in the future may be subject to a reservation of rights by one or more third parties. As a result, any such third party may have certain rights to such intellectual property.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement and defense, of patents and patent applications covering the technology that we license from third parties. We cannot be certain that our in-licensed patent applications (and any patents issuing therefrom) that are controlled by our licensors will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents rights, or lose rights to those patent applications (or any patents issuing therefrom), the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates and proprietary product platform technology that are subject of such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Moreover, we cannot be certain that such activities by our potential future licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, even where we may have the right to control the prosecution of patents and patent applications that we may license to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our potential future licensees, licensors and their counsel that took place prior to the date of assumption of control over patent prosecution.

The patent position of biopharmaceutical companies, including ours and our licensors', is generally uncertain and involves complex legal and factual considerations and, therefore, validity and enforceability cannot be predicted with certainty. Our licensed and co-owned intellectual property may be challenged, deemed unenforceable, invalidated or circumvented. We and our licensors will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that these rights (and the products and services they cover) are protected by valid and enforceable patents, copyrights or trademarks, or are effectively maintained as trade secrets.

Any patents obtained by our licensors or us, may be challenged by re-examination or otherwise invalidated or eventually found unenforceable. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent relating to one of our products, the defendant in such litigation could counterclaim that the asserted patents are invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are common, as are validity challenges by the defendant against the subject patent or related patents before the USPTO. Grounds for a validity challenge could be an alleged failure to meet any of several statutory patentability requirements, including lack of novelty, obviousness, non-enablement, failure to meet the written description requirement, indefiniteness, and/or failure to claim patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected to prosecution of the patent/s at issue intentionally withheld material information from the USPTO or made a misleading statement during prosecution. Additional grounds for an unenforceability assertion include an allegation of misuse or anticompetitive use of patent rights, and an allegation of incorrect inventorship with deceptive intent. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome of any assertion of invalidity and/or unenforceability is unpredictable. If a defendant or third party were to prevail on a legal assertion of invalidity and/or unenforceability, We and our licensors would lose at least part, and perhaps all, of the claims of the challenged patent/s. Such a loss of patent protection could have a material adverse impact on our business.

***We are dependent on patents and proprietary technology. If we fail to adequately protect this intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer.***

Our commercial success will depend in part on our ability to obtain and maintain patent protection sufficient to prevent others from marketing our product candidates, as well as to defend and enforce these patents against infringement and to operate without infringing the proprietary rights of others. Protection of our product candidates from unauthorized use by third parties will depend on having valid and enforceable patents that cover our product candidates or their manufacture or use or on having effective trade secret protection. If our patent applications do not result in issued patents or if our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein. We have a limited number of patents and pending patent applications.

The patent positions of biotechnology companies can be uncertain and involve complex legal and factual questions. This is due to inconsistent application of policies and changes in policy relating to the examination and enforcement of biotechnology patents to date on a global scale. The laws of some countries may not protect intellectual property rights to the same extent as the laws of countries having well-established patent systems, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Also, changes in either patent laws or in the interpretations of patent laws may diminish the value of our intellectual property. We are not able to guarantee that all of our patent applications will result in the issuance of patents, and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we may license from others.

Central provisions of The Leahy-Smith America Invents Act, or the America Invents Act, went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the USPTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the USPTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, USPTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the USPTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the USPTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the USPTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not be the first to file patent applications for our inventions;
- others may independently develop similar or alternative product candidates to any of our product candidates that fall outside the scope of our patents;
- our pending patent applications may not result in issued patents;
- our issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
- we may not develop additional patentable proprietary technology related to our product candidates; and
- we are dependent upon the diligence of our appointed agents in national jurisdictions, acting for and on our behalf, which control the prosecution of pending domestic and foreign patent applications and maintain granted domestic and foreign patents.

An issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing the same or related product candidates or could limit the length of the term of patent protection of our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Patent term extensions may not be available for these patents.

***Our rights to develop and commercialize our product candidates and proprietary product platform may be subject, in part, to the terms and conditions of current and future licenses granted to us by others.***

Some of our licensed rights could provide us with freedom to operate for aspects of our products and services. We may need to obtain additional licenses from others to advance our research, development and commercialization activities.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether, and the extent to which, our products, services, technology and processes infringe on the intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or could increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected products or services, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Absent the license agreements, we may infringe patents subject to those agreements, and, if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs to us and distract our management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses and royalties. We may also be enjoined from selling our products or services, which could adversely affect our ability to offer products or services, our ability to continue operations, and our financial condition.

***If we infringe the rights of third parties, we could be prevented from selling products, forced to pay damages and/or royalties, and forced to defend against litigation.***

We do not believe that the products we are currently developing infringe upon the rights of any third parties or are infringed upon by third parties. However, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs much later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products or product candidates infringe. For example, pending patent applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that is infringed by one or more of our products. In such a case, others may assert infringement claims against us, and should we be found to infringe these patents or impermissibly use their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such third parties' patent rights.

In addition to any damages we might have to pay, we may also be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to use this intellectual property. Each of these penalties may prove to be uneconomical or otherwise impossible. We may fail to obtain any such licenses or intellectual property rights on commercially reasonable terms. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same licensed technologies. In that event, we may be required to spend significant time and resources to develop or license replacement technologies. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business. Conversely, we may not be able to pursue claims against third parties that infringe on our licensed or co-owned technology. Thus, our licensed and co-owned technology may not provide adequate protection against competitors.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Moreover, the cost to us of any litigation or other proceeding relating to our licensed and/or co-owned intellectual property rights, even if resolved in our favor, could be substantial. Any such litigation would divert our management efforts, and we may not have sufficient resources to bring any such action to a successful conclusion. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue operations.

Additionally, because our pipeline may involve additional development candidates that could require the use of proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our development candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to require third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

***We may not be successful in obtaining, through acquisitions, in-licenses or otherwise, necessary rights to our product candidates, proprietary product platform technologies or other technologies.***

We currently have rights to certain intellectual property, through licenses from third parties, to develop our product candidates and proprietary product platform technologies. Some healthcare companies and academic institutions are competing with us in the field of microbiome therapies and may have patents and/or have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. We may also require licenses from third parties for certain technologies that we may be evaluating for use with our current or future product candidates. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates and our proprietary product platform at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

In the event that we try to obtain rights to required third-party intellectual property rights and is ultimately unsuccessful, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates or continue to utilize our existing proprietary product platform technology, which could significantly harm our business, financial condition, results of operations and prospects.

***We rely on our proprietary product platform to identify microbiome therapies. Our competitive position could be materially harmed if our competitors develop a similar platform and develop rival product candidates.***

We rely on know-how, inventions and other proprietary information to strengthen our competitive position. We consider know-how to be our primary intellectual property with respect to our proprietary product platform. Our clinical trials allow us to collect clinical data, which we use as a feedback loop to make improvements to our proprietary product platform. In particular, we anticipate that, with respect to this proprietary product platform, this data may over time be disseminated within the industry through independent development, the publication of journal articles describing the method and the movement of skilled personnel.

We cannot rule out that our competitors may have or obtain the knowledge necessary to analyze and characterize similar data to our known data for the purpose of identifying and developing products that could compete with any of our product candidates. Our competitors may also have significantly greater financial, product development, technical and human resources access to date. Further, our competitors may have significantly greater experience in using translational science methods to identify and develop product candidates.

We may not be able to prohibit our competitors from using technology or methods that are the same as or similar to our proprietary product platform to develop their own product candidates. If our competitors develop associated therapies, our ability to develop and market a promising product or product candidate may diminish substantially, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

***We rely on trade secrets and other forms of non-patent intellectual property protection. If we are unable to protect our trade secrets, other companies may be able to compete more effectively against us.***

We rely on trade secrets to protect certain aspects of our technology, including our proprietary processes for manufacturing and purifying bacteriophage. Trade secrets are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secret information is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to or may not protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

***If we are sued for infringing intellectual property rights of third parties or if we are forced to engage in an interference proceeding, it will be costly and time-consuming, and an unfavorable outcome in that litigation or interference would have a material adverse effect on our business.***

Our ability to commercialize our product candidates depends on our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign patents and patent applications, which are owned by third parties, exist in the general field of anti-infective products or in fields that otherwise may relate to our product candidates. If we are shown to infringe, we could be enjoined from the use or sale of the claimed invention if we are unable to prove that the patent is invalid. In addition, because patent applications can take many years to issue, there may be currently pending patent applications, unknown to us, that may later result in issued patents that our product candidates may infringe or that may trigger an interference proceeding regarding one of our owned or licensed patents or applications. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe or that may become involved in an interference proceeding.

The biotechnology and pharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. For so long as our product candidates are in clinical trials, we believe our clinical activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our clinical investigational drug product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. While we attempt to ensure that our active clinical investigational drugs and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights, we cannot be certain they do not, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may be exposed to future litigation based on claims that our product candidates, the methods we employ to manufacture them or the uses for which we intend to promote them infringe the intellectual property rights of others. Our ability to manufacture and commercialize our product candidates may depend on our ability to demonstrate that the manufacturing processes we employ and the use of our product candidates do not infringe third-party patents. If third-party patents were found to cover our product candidates or their use or manufacture, we could be required to pay damages or be enjoined and therefore unable to commercialize our product candidates, unless we obtained a license. A license may not be available to us on acceptable terms, if at all.

***We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.***

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that, if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her inventions. We generally enter into assignment of invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to our service invention rights, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees or be forced to litigate such claims, which could negatively affect our business.

**Risks Related to Our Reliance on Third Parties**

***We rely, and continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We continue to rely on third parties, such as contract research organizations, or CROs, and clinical investigators, to conduct and manage our clinical trials.

Our reliance on these third parties for research and development activities will reduce our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which we must comply. We are also required to register ongoing clinical trials and post the results of completed clinical trials in a government-sponsored database, clinicaltrials.gov, within specified time frames. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, terminated or need to be repeated. If any of the foregoing occurs, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

***Third-party relationships are important to our business. If we are unable to maintain our collaborations or enter into new relationships, or if these relationships are not successful, our business could be adversely affected.***

We have limited capabilities for product development and do not yet have any capability for sales, marketing or distribution. Accordingly, we enter into relationships with other companies and academic institutions to provide us with important technology, and we may receive additional technology and funding under these and other collaborations in the future. The relationships we enter into may pose a number of risks, including the following:

- third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- current and future third parties may not perform their obligations as expected;
- current and future third parties may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;

- third parties may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- current and future third parties could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the third parties believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our current or future third parties as competitive with their own product candidates or products, which may cause such third parties to cease to devote resources to the commercialization of our product candidates;

- current and future third parties may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

- current and future third parties with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with current or future third parties, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- current and future third parties may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- current and future third parties may infringe the intellectual property rights of others, which may expose us to litigation and potential liability;

- current and future third parties may infringe regulatory frameworks (such as but not limited to cybersecurity and/or privacy frameworks), which may expose us to litigation and potential liability or require or lead us to terminate relationships with them;

- if a current or future third party is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and

- current and future relationships may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our relationships do not result in the successful discovery, development and commercialization of products or if one of our third-party collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology and product candidates could be delayed, and we may need additional resources to develop product candidates and our technology. Additionally, if any of our current or future third-party collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators, and our reputation in the business and financial communities could be adversely affected.

Relationships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of a collaborator's resources and expertise, the terms and conditions of a proposed collaboration and a proposed collaborator's evaluation of a number of factors.

***We may not be successful in maintaining or establishing collaborations, which could adversely affect our ability to develop and, if required regulatory approvals are obtained, commercialize our product candidates.***

In the future, in order to advance our clinical development, or in connection with any potential out-licensing of product candidates or technologies, we may seek to enter into collaboration agreements. In addition, we may consider entering into collaboration arrangements with medical technology, pharmaceutical or biotechnology companies and/or seek to establish strategic relationships with marketing partners for the development, sale, marketing and/or distribution of our product candidates within or outside of the United States. If we are unable to reach agreements with potential collaborators, then we may fail to meet our business objectives for the affected product candidates or programs. Collaboration arrangements are complex and time-consuming to negotiate, document and implement, and we may not be successful in our efforts, if any, to establish and implement collaborations or other alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us, and the success of any such collaboration will depend heavily on the efforts and activities of our collaborators. Moreover, our collaboration agreement could be terminated or not renewed by a third party at a time that is costly or damaging to us. Any failure to engage successful collaborators could cause delays in our product development and/or commercialization efforts, which could harm our financial condition and operational results.

**Risks Related to Our Operations in Israel**

***The Israeli government grants we have received for research and development expenditures restrict our ability to manufacture products and transfer technology outside of Israel and requires us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received, together with interest and penalties.***

Our research and development efforts have been financed, in part, through the grants that we have received from the Israeli Innovation Authority, or the IIA. We, therefore, must comply with the requirements of the Israel Encouragement of Research and Development in Industries, or the Research Law. For the years ended December 31, 2021 and 2020, we recorded grants totaling $3.7 million, $0.5 million, from the IIA, respectively. The grants represented 13.7% and 2.7% of our gross research and development expenditures for the years ended December 31, 2021 and 2020, respectively.

Under the Research Law, we are required to manufacture the major portion of each of our products developed using these grants in the State of Israel or otherwise ask for special approvals. We may not receive the required approvals for any proposed transfer of manufacturing activities. Even if we receive approval to manufacture products developed with government grants outside of Israel, the royalty rate may be increased, and we may be required to pay up to 300% of the grant amounts, plus interest, depending on the manufacturing volume that is performed outside of Israel. This restriction may impair our ability to outsource manufacturing or engage in our own manufacturing operations for those products or technology.

Additionally, under the Research Law, we are prohibited from transferring, including by way of license, the IIA-financed technology and related intellectual property rights and know-how outside of the State of Israel, except under limited circumstances and only with the approval of the IIA Research Committee. We may not receive the required approvals for any proposed transfer, and, even if received, we may be required to pay the IIA a portion, to be set by the IIA, in its discretion and taking into account the circumstances, upon its approval of such transaction, of the consideration or milestone and royalty payments that we receive upon any sale or out-licensing of such technology to a non-Israeli entity, up to 600% of the grant amounts plus interest.

These restrictions may impair our ability to sell our technology assets or to perform or outsource manufacturing outside of Israel or otherwise transfer our know-how outside of Israel and may require us to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. In addition, any change of control and any change of ownership of our Common Stock that would make a non-Israeli citizen or resident an "interested party," as defined in the Research Law, requires prior written notice to the IIA, and our failure to comply with this requirement could, under certain circumstances, result in criminal liability.

These restrictions will continue to apply even after we have repaid the full amount of royalties on the grants.

***We have received, and may continue to receive, Israeli governmental grants to assist in the funding of our research and development activities. If we lose our funding from these research and development grants, we may encounter difficulties in the funding of future research and development projects and implementing technological improvements, which would harm our operating results.***

Through December 31, 2021, we had received an aggregate of $5.6 million in the form of grants from the IIA. BiomX Ltd. was formed as an incubator company as part of the FutuRx incubator, and, until 2017, the majority of our funding was from IIA grants and funding by the incubator, which is supported by the IIA. We continued to apply for and receive IIA grants after we left the incubator. The requirements and restrictions for such grants are found in the Research Law. Under the Research Law, royalties of 3% to 3.5% on the revenue derived from sales of products or services developed in whole or in part using these IIA grants are payable to the Israeli government. We developed both of our platform technologies, at least in part, with funds from these grants, and, accordingly, we would be obligated to pay these royalties on sales of any of our product candidates that achieve regulatory approval. As long as the manufacturing of our product candidates takes place in Israel and no technology funded with IIA grants is sold or out licensed to a non-Israeli entity, the maximum aggregate royalties paid generally would not exceed 100% of the grants made to us, plus annual interest equal to the 12-month LIBOR rate applicable to dollar deposits, as published on the first business day of each calendar year. The United Kingdom's Financial Conduct Authority, which regulates LIBOR, announced in July 2017 that it will no longer persuade or require banks to submit rates for LIBOR after 2021. In September 2021, the Bank of Israel, which determines annual interest rates, published a directive which stated that annual interest at a variable rate linked to the LIBOR rate for loans in U.S. dollars will be replaced by the Secured Overnight Financing Rate, or the SOFR, in June 2023. While it is not currently possible to determine precisely whether, or to what extent, the replacement of LIBOR with SOFR would affect us, the implementation of SOFR may increase our financial liabilities to the IIA. Management continues to monitor the status and discussions regarding SOFR. We are not yet able to reasonably estimate the expected impact. As of December 31, 2021, the balance of the principal and interest in respect of our commitments for future payments to the IIA totaled approximately $5.4 million. As part of funding our current and planned product development activities, we have submitted follow-up grant applications for new grants.

These grants have funded some of our personnel, development activities with subcontractors, and other research and development costs and expenses. However, if these awards are not funded in their entirety or if new grants are not awarded in the future, due to, for example, IIA budget constraints or governmental policy decisions, our ability to fund future research and development and implement technological improvements would be impaired, which would negatively impact our ability to develop our product candidates.

***Potential political, economic and military instability in the State of Israel, where the majority of our senior management and our research and development facilities are located, may adversely affect our results of operations.***

Our headquarters and principal offices and most of our operations are located in the State of Israel. In addition, all but one of our key employees and officers are residents of Israel. Accordingly, political, economic and military conditions in Israel directly affect our business.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could affect adversely our operations. Ongoing and revived hostilities or other Israeli political or economic factors could harm our operations, product development and results of operations.

Although Israel has entered into various agreements with Egypt, Jordan, the Palestinian Authority and with various states in the Persian Gulf, there has been a continuous unrest and terrorist activity with varying levels of severity, the most recent of which was the armed conflict with Hamas in May 2021. In addition, Israel faces threats from more distant neighbors, in particular, Iran. Our insurance policies do not cover us for the damages incurred in connection with these conflicts or for any resulting disruption in our operations. The Israeli government, as a matter of law, provides coverage for the reinstatement value of direct damages that are caused by terrorist attacks or acts of war; however, the government may cease providing such coverage or the coverage might not be enough to cover potential damages. In the event that hostilities disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and products, our operations may be materially adversely affected.

Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies, whether as a result of hostilities in the region or otherwise. In addition, there have been increased efforts by activists to cause companies, research institutions and consumers to boycott Israeli goods and cooperation with Israeli-related entities based on Israeli government policies. Such actions, particularly if they become more widespread, may adversely impact our ability to cooperate with research institutions and collaborate with other third parties. Any hostilities involving Israel, any interruption or curtailment of trade or scientific cooperation between Israel and its present partners, or a significant downturn in the economic or financial condition of Israel could adversely affect our business, financial condition and results of operations. We may also be targeted by cyber terrorists specifically because we are an Israeli-related company.

***Under applicable employment laws, we may not be able to enforce covenants not to compete.***

We generally enter into noncompetition agreements with our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work, and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli labor courts have required employers seeking to enforce noncompete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer that have been recognized by the courts, such as the protection of a company's trade secrets or other intellectual property.

***Our operations may be disrupted by the obligations of personnel to perform military service.***

Some of our employees based in Israel may be called upon to perform annual military reserve duty and, in emergency circumstances, could be called to immediate and unlimited active duty. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of one or more of our executive officers or other key employees. Such disruption could materially adversely affect our business and results of operations.

***The tax benefits that are available to us if and when we generate taxable income require us to meet various conditions and may be prevented or reduced in the future, which could increase our costs and taxes.***

If and when we generate taxable income, we would be eligible for certain tax benefits provided to "Technologic Preferred Enterprise" and/or "Preferred Enterprise" as defined under the Encouragement of Capital Investment Law -1959, or the "Law, and its regulations, as amended and, accordingly, could be subject to a reduced corporate tax rate on its income that will meet the provisions of the Law (ranging between 7.5%-16%). To the extent that we are not eligible to obtain such statuses, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies is 23%. The benefits available to us in accordance to the Law and its regulations are subject to the fulfillment of conditions stipulated in the Law and the regulations. Further, in the future, these tax benefits may be reduced or discontinued.

***It may be difficult to enforce a U.S. judgment against us or our officers and directors in Israel or the United States or to assert U.S. securities laws claims in Israel or serve process on our officers and directors.***

Not all of our directors or officers are residents of the United States, and most of their and our assets are located outside the United States. Service of process upon us or our non-U.S. resident directors and officers may be difficult to obtain within the United States. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our non-U.S. officers and directors, because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law, and not U.S. law, is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Additionally, Israeli courts might not enforce judgments obtained in the United States against us or our non-U.S. directors and executive officers, which may make it difficult to collect on judgments rendered against us or our non-U.S. officers and directors.

Moreover, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases), if its enforcement is likely to prejudice the sovereignty or security of the State of Israel, if it was obtained by fraud or in the absence of due process, if it is at variance with another valid judgment that was given in the same matter between the same parties, or if a suit in the same matter between the same parties was pending before a court or tribunal in Israel at the time the foreign action was brought.

**Risks Related to Manufacturing and Supply**

***We rely on third parties to manufacture our clinical supply of product candidates and we intend to rely on third parties to produce and process our products, if approved.***

We currently rely on outside vendors to supply raw materials and other important components, such as lab equipment. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We will make changes as it works to optimize the manufacturing process for our product candidates, and we cannot be sure that even minor changes in the process will result in therapies that are safe and effective.

The facilities used to manufacture our product candidates must be approved by the FDA or equivalent foreign regulatory agencies pursuant to inspections that will be conducted after we submit a marketing application to the FDA or equivalent foreign regulatory agency. Additionally, any facilities used for the manufacture of product candidates commercialized for non-therapeutic uses will be subject to inspection by the FDA and foreign regulatory agencies. We do not currently control all aspects of the manufacturing process of, and are currently largely dependent on, our contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for manufacture of our product candidates. If and when our manufacturing facility becomes operational, we will be responsible for compliance with cGMP requirements. If we or our contract manufacturers cannot successfully manufacture in conformance with our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we and they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities with respect to the manufacture of our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or an equivalent foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We have limited experience manufacturing our product candidates for purposes of clinical trials for therapeutic indications or for non-therapeutic clinical studies or trials. We opened our own manufacturing facility at our headquarters in Ness Ziona, Israel in the third quarter of 2019. We cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

***Our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.***

Our product candidates require certain specialty raw materials, some of which we obtain from small companies with limited resources and experience to support a commercial product. These third-party suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We do not currently have contracts in place with all of the suppliers that we may need at any point in time and, if needed, may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

**Risks Related to Our Common Stock**

***A significant number of shares of our Common Stock are subject to issuance upon exercise of outstanding warrants and options, which upon such exercise may result in dilution to our security holders.***

As of December 31, 2021, we had an aggregate of 13,652,974 warrants outstanding to purchase an aggregate of up to 9,215,475 shares of Common Stock with a weighted average exercise price of $9.51, certain of which are included in our outstanding units, certain of which were issued in private placements and certain of which are traded on the NYSE American under the symbol "PHGE.WS," or the Outstanding Warrants, in each case subject to adjustment. To the extent such warrants are exercised, additional shares of our Common Stock will be issued, which will result in dilution to the then existing holders of Common Stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our Common Stock.

In addition, as of December 31, 2021, we had outstanding vested and unvested options to purchase 4,084,549 shares of our Common Stock. To the extent any of these options are exercised, additional shares of Common Stock will be issued that will generally be eligible for resale in the public market (subject to limitations under Rule 144 under the Securities Act with respect to shares held by our affiliates), which will result in dilution to our security holders. We plan to grant additional options and warrants in the future. The issuance of additional securities could also have an adverse effect on the market price of our Common Stock.

***We have never paid dividends on our Common Stock, and we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future.***

We have never declared or paid cash dividends on our Common Stock. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our Common Stock will be our stockholders' sole source of gain for the foreseeable future.

***We may be unable to maintain the listing of our securities in the future.***

Our Common Stock and certain of our warrants currently trade on the NYSE American and our Common Stock currently trades on the Tel Aviv Stock Exchange. If our Common Stock or warrants are subsequently delisted, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for the post-transaction company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

***As a "smaller reporting company" we are permitted to provide less disclosure than larger public companies, which may make our Common Stock less attractive to investors.***

We are currently a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act. As a smaller reporting company, we are eligible to take advantage of certain exemptions from various reporting requirements applicable to other public companies. Consequently, it may be more challenging for investors to analyze our results of operations and financial prospects which may result in less investor confidence. Investors may find our Common Stock less attractive as a result of our smaller reporting company status. If some investors find our Common Stock less attractive, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

**General Risk Factors**

***Our success depends, in part, on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on Jonathan Solomon, our chief executive officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

Our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists is critical to our success. Competition for qualified personnel in the biotechnology field is intense, particularly in Israel where our headquarters are located. We face competition for personnel from other biotechnology and pharmaceutical companies, universities, public and private research institutions and other organizations. We also face competition from other more well-funded and well-established businesses, and we may also be viewed as a riskier choice from a job stability perspective due to our relatively newer status than longer existing biotech and pharmaceutical companies. We may not be able to attract and retain qualified personnel on acceptable terms given the competition for such personnel. If we are unsuccessful in our retention, motivation and recruitment efforts, we may be unable to execute our business strategy.

***Expectations relating to environmental, social and governance (ESG) programs may impose additional costs and expose us to new risks.***

There is an increasing focus from certain investors and other key stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. As a result, there is an increased emphasis on corporate responsibility ratings and a number of third parties provide reports on companies in order to measure and assess corporate responsibility performance. In addition, the ESG factors by which companies' corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We risk damage to our brand and reputation if our corporate responsibility procedures or standards do not meet the standards set by various constituencies. We may be required to make investments in matters related to ESG, which could be significant and adversely impact our results of operations. Furthermore, if our competitors' corporate responsibility performance is perceived to be greater than ours, potential or current investors may elect to invest with our competitors instead. In addition, if we communicate certain initiatives and goals regarding ESG matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other key stakeholders or our initiatives are not executed as planned, our reputation and financial results could be materially and adversely affected.

***Failure to comply with health and data protection laws and regulations could lead to claims, government enforcement actions (which could include civil or criminal penalties), regulatory actions, private litigation and/or adverse publicity and could negatively affect our operating results and business.***

We may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state consumer privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Additional requirements may also be imposed by international data protection laws. In this context, Regulation 2016/679 of the GDPR (in addition to many other international data protection laws) may have an impact on our operations when we collect and/or process personal data of individuals located in the European Union. The GDPR has applied since May 25, 2018 (replacing previously applicable data protection frameworks) and has an extraterritorial reach. The GDPR allows members states to introduce specific requirements in relation to certain areas, including processing of special categories of data, and we may face further restrictions and non-compliance risks under such national frameworks. We have not yet assessed whether its activities might be caught by the GDPR.

Because of the types of data we collect and process, which may involve health, biometric and genetic data, we may face high risks for non-compliance with the GDPR rules (or local declinations of GDPR-rules across the different European Union Member States), as these types of data are considered as special categories of data and are granted higher protection. The risks are further increased considering the diverging approach in the European Union as to the rules, requirements and frameworks in relation to the processing of personal data in clinical trials (in matters such as the choice of the legal basis for the processing of data, the possible uses of the personal data collected, etc.) and the interplay with other relevant frameworks. The GDPR introduced stringent data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual worldwide turnover. Supervisory authorities also have the ability to restrict our processing activities if those are deemed not to be in compliance with the GDPR (or local declinations); this may significantly impact the way we conduct our activities. The GDPR imposes numerous requirements for the collection, use and disclosure of personal data, including high standards for consent to be valid, and specific information to be provided to individuals about how their personal data is used, the obligation to notify regulators and (in some cases) to communicate to affected individuals of personal data breaches, extensive new internal privacy governance requirements and obligations to allow individuals to exercise their strengthened privacy rights (e.g., the right to access, correct and delete their personal data, to withdraw their consent, etc.), and obligations when contracting with third parties such as service providers, CROs, etc. In addition, the GDPR includes restrictions on data transfers outside the European Economic Area, or EEA. The actual mechanisms made available under GDPR to transfer such personal data have received heightened regulatory and judicial scrutiny. If we cannot rely on existing mechanisms for transferring personal data from the EEA, the United Kingdom, or other jurisdictions, we may be unable to transfer personal data in those regions. Further, the United Kingdom's vote in favor of exiting the European Union, often referred to as "Brexit," has created uncertainty as to whether or not the United Kingdom data protection legislation will depart from the GDPR and how data transfers to and from the United Kingdom will be regulated.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Such laws and regulations could limit our ability to use and share personal or other data, thereby increasing our costs and harming our business and financial condition. Failure to comply with U.S. and international data protection laws and regulations could result in claims, government enforcement actions (which could include civil or criminal penalties), regulatory actions, private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business. Finally, we may be required to disclose personal data pursuant to demands from government agencies, from law enforcement agencies, and from intelligence agencies. This disclosure may result in a failure or perceived failure by us to comply with data privacy laws, rules, and regulations and could result in proceedings or actions against us in the same or other jurisdictions, and could have an adverse impact on our reputation and brand.

***Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, and foreign equivalent legislation, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- federal civil and criminal false claims laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and

- European Union and other foreign provisions.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage, security requirements intended to prevent the unauthorized sale of pharmaceutical products and, in some foreign countries, including the European Union countries, mandatory anti-counterfeit features.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. The failure to comply with any of these laws or regulatory requirements could subject us to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.***

We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

***Our business and operations might be adversely affected by security breaches, including any cybersecurity incidents.***

We depend on the efficient and uninterrupted operation of our computer and communications systems, and those of our consultants, contractors and vendors, which we use for, among other things, sensitive company data, including our intellectual property, financial data and other proprietary business information.

While certain of our operations have business continuity and disaster recovery plans and other security measures intended to prevent and minimize the impact of IT-related interruptions, our IT infrastructure and the IT infrastructure of our consultants, contractors and vendors are vulnerable to damage from cyberattacks, computer viruses, unauthorized access, electrical failures and natural disasters or other catastrophic events. We could experience failures in our information systems and computer servers, which could result in an interruption of our normal business operations and require substantial expenditure of financial and administrative resources to remedy. System failures, accidents or security breaches can cause interruptions in our operations and can result in a material disruption of our targeted phage therapies, product candidates and other business operations. The loss of data from completed or future studies or clinical trials could result in delays in our research, development or regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur regulatory investigations and redresses, penalties and liabilities and the development of our product candidates could be delayed or otherwise adversely affected.

Even though we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. For example, we are not insured against terrorist attacks or cyberattacks. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay the development of our product candidates.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. We have experienced and expect to continue to experience actual and attempted cyber-attacks of our IT networks, such as through phishing scams and ransomware. Although none of these actual or attempted cyber-attacks has had a material adverse impact on our operations or financial condition, we cannot guarantee that any such incidents will not have such an impact in the future.

***We incur significant costs operating as a public company.***

As a public company, we incur significant costs in connection with our directors and officers insurance, paying for service providers such as legal and accounting as well as other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the NYSE American to implement provisions of the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and the Public Company Accounting Oversight Board impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. These expenses will likely increase in the future, particularly after we cease to be an “emerging growth company” if we are also no longer a “smaller reporting company” as a result of additional corporate governance and disclosure requirements under the Sarbanes-Oxley Act, the Dodd-Frank Act, and SEC rules and regulations.

The rules and regulations applicable to public companies result in us continuing to incur substantial legal and financial compliance costs. These costs increase our net loss or decrease any net income and may require us to reduce costs in other areas of our business.

***Sales of a substantial number of shares of our Common Stock in the public market by our existing stockholders could cause our stock price to decline.***

Sales of a substantial number of shares of our Common Stock in the public market or the perception that these sales might occur, could depress the market price of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our Common Stock.

***The market price of our Common Stock and other securities may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.***

The stock markets in general and the markets for biotechnology stocks have experienced extreme volatility. The market for the common stock of smaller companies such as ours is characterized by significant price volatility when compared to the shares of larger, more established companies that trade on a national securities exchange and have large public floats, and our share price is more volatile than the shares of such larger, more established companies for the indefinite future.

In addition to the factors discussed in this "Risk Factors" section, price declines in our Common Stock (and other securities) could also result from general market and economic conditions and a variety of other factors, including:

- adverse results or delays in our clinical trials;
- adverse actions taken by regulatory agencies with respect to our product candidates, clinical trials or the manufacturing processes of our product candidates;
- announcements of technological innovations, patents or new products by our competitors;
- regulatory developments in the United States and foreign countries;
- any lawsuit involving us or our product candidates;
- announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;
- developments concerning any strategic alliances or acquisitions we may enter into;
- actual or anticipated variations in our operating results;
- changes in recommendations by securities analysts or lack of analyst coverage;
- deviations in our operating results from the estimates of analysts;
- our inability, or the perception by investors that we will be unable, to continue to meet all applicable requirements for continued listing of our Common Stock on the NYSE American, and the possible delisting of our Common Stock;
- sales of our Common Stock by our executive officers, directors and principal stockholders or sales of substantial amounts of Common Stock; and
- loss of any of our key scientific or management personnel.

Additionally, market prices for securities of biotechnology companies historically have been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. Furthermore, our business may be adversely impacted by risks, or the public perception of the risks, related to a pandemic or other health crisis, such as the COVID-19 or as a result of the Russian invasion of Ukraine and world sanctions on Russia, Belarus, and related parties. A significant outbreak of contagious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. Any such lawsuit could consume resources and management time and attention, which could adversely affect our business.

***If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of our company, our stock price and trading volume could be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our stock adversely, provide more favorable relative recommendations about our competitors or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If any analyst who may cover us ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

Our corporate headquarters are located in Ness Ziona, Israel. During the second quarter of 2021, we moved into a new 28,610 square feet facility of office and laboratory space, including a new 6,500 square foot manufacturing facility. The lease expires in 2025, with an option to extend the term by five years. This facility has been designed with the capacity to produce clinical quantities of our product candidates required for clinical development. We also lease 3,770 square feet of office space located in Connecticut. We believe our facilities are sufficient to meet our current needs.

**ITEM 3. LEGAL PROCEEDINGS**

We may be subject to legal proceedings, investigations and claims incidental to the conduct of our business from time to time. We are not currently a party to any material litigation or other material legal proceedings brought against us.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our shares of Common Stock, Public Units, and Public Warrants are traded on NYSE American under the symbols PHGE, PHGE.U and PHGE.WS, respectively.

Our shares of Common Stock are also traded on the Tel Aviv Stock Exchange under the symbol "PHGE".

**Holders of Record**

As of March 25, 2022, there were 29,779,249 issued and outstanding shares of our Common Stock held by 72 stockholders of record. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of shares of Common Stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

**Dividends**

We have not paid any cash dividends on our Common Stock to date and do not intend to pay cash dividends. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our Board of Directors at such time. Further, the Hercules Loan Agreement limits our ability to declare or pay dividends, and if we incur additional indebtedness, our ability to declare dividends may be further limited by restrictive covenants we may agree to in connection therewith.

### ITEM 6. [RESERVED.]

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the notes thereto contained elsewhere in this report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those discussed in any forward-looking statement because of various factors, including those described in the sections titled "Cautionary Statement Regarding Forward-Looking Statements" and "Risk Factors" in this Annual Report.*

We are a clinical stage microbiome product discovery company developing products using both natural and engineered phage technologies designed to target and destroy specific harmful bacteria associated with chronic diseases, such as CF, AD, as well as IBD, PSC and CRC. Bacteriophage or phage are bacterial, species-specific, strain-limited viruses that infect, amplify and kill the target bacteria and are considered inert to mammalian cells. By utilizing proprietary combinations of naturally occurring phage and by creating novel phage using synthetic biology, we develop phage-based therapies intended to address both large-market and orphan diseases.

Since BiomX Ltd.'s inception in 2015, and since the Business Combination, we have devoted substantially all our resources to organizing and staffing our company, raising capital, acquiring rights to or discovering product candidates, developing our technology platforms, securing related intellectual property rights, and conducting discovery, research and development and clinical activities for our product candidates. We do not have any products approved for sale, and we have not generated any revenue from product sales. As we advance our product candidates, we expect our expenses to remain significant. To date, we have funded our operations with proceeds from sales of Common Stock and preferred shares. Through December 31, 2021, we had received gross proceeds of approximately $146 million from sales of our securities. To date, we received approximately $634 thousand from our collaboration agreements and recorded a reduction from research and development expenses of $634 thousand.

Since BiomX Ltd.'s inception in 2015, and since the Business Combination, we have incurred significant operating losses. Our ability to generate revenue from product sales sufficient to achieve profitability will depend on the successful development of, the receipt of regulatory approval for, and eventual commercialization of one or more of our product candidates. Our net losses were approximately $36.2 million and $30.1 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $108.5 million and expect that for the foreseeable future we will continue to incur significant expenses as we advance our product candidates from discovery through preclinical development and clinical trials and seek regulatory approval of our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with in-licensing or acquiring additional product candidates.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations. We may implement cost reduction strategies, which may include amending, delaying, limiting, reducing or terminating one or more of our programs or ongoing or planned clinical trials of our product candidates.

On December 31, 2021, we had cash, cash equivalents and restricted cash of $63.1 million. We believe that our existing cash and cash equivalents and short-term deposits will enable us to fund our operating expenses and capital expenditure requirements until at least the end of 2023, as discussed further below under "-Liquidity and Capital Resources"

**Components of Our Consolidated Results of Operations**

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the near future. If development efforts for our product candidates are successful and result in any necessary regulatory approvals or otherwise lead to any commercialized products or additional license agreements with third parties, we may generate revenue in the future from product sales or payments from collaboration or license agreements with third parties.

Operating Expenses

*Research and Development Expenses, net*

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred, offset by IIA grants and, to a lesser degree, income from research and development collaboration agreements. These expenses include:

- development and operation of our proprietary platform;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as CROs and contract manufacturing organizations, as well as consultants, subcontractors and key opinion leaders providing scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials;
- license maintenance fees and milestone fees incurred in connection with various license agreements;
- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expenses for employees engaged in research and development functions, as well as external costs, such as fees paid to outside consultants engaged in such activities;
- costs related to compliance with regulatory requirements and legal fees relating to patent matters; and
- depreciation and other expenses.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee the research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by program:

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| | USD In thousands | |
| BX001 (discontinued in 2021) | 1,792 | 2,845 |
| BX002/BX003 | 1,294 | 3,206 |
| BX004 | 4,506 | 152 |
| BX005 | 2,044 | 28 |
| CRC | 441 | 592 |
| Salaries and related benefits (including stock-based compensation) | 14,057 | 11,026 |
| Depreciation | 986 | 653 |
| Infrastructure & other unallocated research and development or R&D expenses | 2,182 | 1,593 |
| Less grants from the IIA and consideration from collaboration agreements | (4,626) | (678) |
| Total research and development expenses, net | 22,676 | 19,417 |

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years, particularly as we increase personnel costs, including stock-based compensation, contractor costs and facilities costs, as we continue to advance the development of our product candidates. We also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license agreements to acquire the rights to our product candidates.

*General and Administrative Expenses*

General and administrative expenses consist primarily of salaries, related benefits, travel and stock-based compensation expenses for personnel in executive, finance, corporate, business development and administrative functions. General and administrative expenses also include legal fees relating corporate and securities matters; professional fees for accounting, tax and audit services; insurance costs; travel expenses; and facility-related expenses, including rent, as well as operating related costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will continue to incur significant accounting, audit, legal, regulatory, compliance, directors' and officers' insurance costs as well as investor and public relations expenses associated with being a public company. We anticipate the additional costs for these services will increase our general and administrative expenses in the future. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

*Amortization of intangible assets*

Intangible assets consist of in-process research and development, amortized for a period of three years, that started on January 1, 2020.

*Interest expenses*

Interest expense consists of interest incurred under the Hercules Loan Agreement.

*Financial expenses, net*

Financial expenses, net consist primarily of income or expenses related to revaluation of foreign currencies and interest income on our bank deposits and money market funds.

**Results of Operations**

***Comparison of the Years Ended December 31, 2021 and 2020***

The following table summarizes our consolidated results of operations for the years ended December 31, 2021 and 2020:

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| | USD In thousands | |
| R&D expenses, net | 22,676 | 19,417 |
| Amortization of intangible assets | 1,519 | 1,518 |
| General and administrative expenses | 11,267 | 9,323 |
| **Operating loss** | 35,462 | 30,258 |
| Interest expenses | 699 | - |
| Financial income, net | (2) | (172) |
| Tax expenses | 67 | - |
| **Net Loss** | 36,226 | 30,086 |

R&D expenses, net (net of grants received from the IIA and consideration from research collaborations) were $22.7 million for the year ended December 31, 2021, compared to $19.4 million for the year ended December 31, 2020. The increase of $3.3 million, or 17%, in the year ended December 31, 2021 compared to the prior year, is primarily due to the following:

- an increase of $3.7 million of clinical activities and expenses related to conducting pre-clinical and clinical trials of our product candidates;
- an increase of $3.1 million in salaries and related expenses, mainly due to the growth in the number of employees; and
- a decrease of $3.2 million that resulted from receiving higher IIA grants.

The Company recorded grants from the IIA totaling $3.7 million and $0.5 million for the years ended December 31, 2021 and December 31, 2020, respectively.

Amortization of intangible assets remained consistent from 2020 to 2021.

General and administrative expenses were $11.3 million for the year ended December 31, 2021, compared to $9.3 million for the year ended December 31, 2020. The increase of $2.0 million, or 22%, is primarily due to the following:

- an increase of $0.9 million in expenses associated with operating as a public company, such as directors' and officers' insurance, listing fees and investor relations;
- an increase of $0.5 million in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees ; and
- an increase of $0.4 million in rent and related expenses as well as operational expenses resulting from moving into our new facility in April 2021.

Interest expenses were $0.7 million for the year ended December 31, 2021. The Company had no interest expenses for the year ended December 31, 2020. The increase of $0.7 million, or 100%, is due interest payments accrued under the Hercules Loan Agreement, entered into in August 2021.

Financial income, net was $2 thousand for the year ended December 31, 2021, compared to $172 thousand for the year ended December 31, 2020. The decrease of $170 thousand, or 99%, is primarily due to U.S. dollar/NIS exchange rate differences and the decrease in interest rates on bank deposits and money market funds.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since BiomX Ltd.'s inception in 2015, we have not generated any revenue from sales of our products and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sale of our Common Stock and preferred shares, venture debt, IIA grants and funds from collaboration agreements and through the Business Combination. Through December 31, 2021, we had received gross cash proceeds of approximately $146 million from sales of our Common Stock and preferred shares. In August 2021, we borrowed $15.0 million under the Hercules Loan Agreement. In addition, in 2021 and 2020 we received approximately $3.2 million and $0.7 million from our collaboration agreements and grants from the IIA, respectively.

Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation.

On December 4, 2020, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on December 11, 2020. In addition, on December 4, 2020, we entered into the Sale Agreement, with Jefferies, pursuant to which we may issue and sell shares of our Common Stock having an aggregate offering price of up to $50,000,000 from time to time through Jefferies. We are not obligated to make any sales of Common Stock under the Sale Agreement. Through December 31, 2021, we sold an aggregate of 754,140 shares of Common Stock pursuant to the Sale Agreement for aggregate gross proceeds of $5,413 thousands. From January 1, 2022 through March 25, 2022, we sold an aggregate of 26,011 shares of Common Stock pursuant to the Sale Agreement for aggregate gross proceeds of $36,406. Subject to any limitations on aggregate amounts as a result of the value of our Common Stock owned by non-affiliates that are imposed by SEC regulations, we may continue to sell shares under the Sale Agreement and otherwise to use our shelf registration statement to raise additional funds from time to time.

On August 16, 2021 we entered into the Hercules Loan Agreement with Hercules, with respect to a venture debt facility. Under the Hercules Loan Agreement, Hercules provided the Company with access to a term loan with an aggregate principal amount of up to $30,000, available in three tranches, subject to certain terms and conditions. The first tranche of $15,000 was advanced to the Company on the date the Hercules Loan Agreement was executed. Upon the occurrence of specified milestones and continuing through December 31, 2022, a loan in the aggregate principal amount of up to $10,000, and upon the occurrence of specified milestones and continuing through September 30, 2023, a loan in the aggregate principal amount of up to $5,000, may become available. The milestones for the remaining tranches have not yet been reached as of December 31, 2021.

We believe that our existing cash resources will be sufficient to meet our capital requirements and fund our operations for at least until the end of 2023. In the future we will likely require or desire additional funds to support our operating expenses and capital requirements or for other purposes, such as acquisitions, and may seek to raise such additional funds through public or private equity or debt financings or collaborative agreements or from other sources, as we are doing now with the Sale Agreement and the Hercules Loan Agreement. However, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption due to COVID-19 or other reasons, such as the Russia–Ukraine military conflict, persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity to support our operating expenses and capital requirements or to make investments for other purposes, such as acquisitions.

We have no other commitments to obtain additional financing, except for our commitment under the Securities Purchase Agreement with the Cystic Fibrosis Foundation, signed in December 2021, and cannot assure you that additional financing will be available at all or, if available, that such financing would be obtainable on terms favorable to us and would not be dilutive. Our future liquidity and cash requirements will depend on numerous factors, including the introduction of new products as well as the ability to continue to maintain controls over our operating expenditures.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| | USD In thousands | |
| Net cash used in operating activities | (27,573) | (24,447) |
| Net cash provided by (used in) investing activities | 16,173 | (10,857) |
| Net cash provided by financing activities | 37,280 | 134 |
| Effect of exchange rate changes on cash and cash equivalents and restricted cash | (25) | - |
| Net increase (decrease) in cash and cash equivalents | 25,855 | (35,170) |

**Operating Activities**

During the year ended December 31, 2021, operating activities used $27.6 million of net cash, primarily due to a net loss of $36.2 million and by net cash used by changes in our operating assets and liabilities of $3.2 million and non-cash charges of $5.6 million. Non-cash charges for the year ended December 31, 2021 mainly consisted of stock-based compensation expenses of $3.2 million and depreciation and amortization of $2.6 million, partially offset by revaluation of contingent liabilities expenses of $0.5 million. Net changes in our operating assets and liabilities for the year ended December 31, 2021 consisted primarily of an increase in trade account payables of $0.4 million, and an increase in other account payables of $2.7 million.

During the year ended December 31, 2020, operating activities used $24.4 million of net cash, primarily due to a net loss of $30.1 million and by net cash used by changes in our operating assets and liabilities of $0.5 million and non-cash charges of $5.2 million. Non-cash charges for the year ended December 31, 2020 mainly consisted of stock-based compensation expenses of $2.9 million and depreciation and amortization of $2.2 million, partially offset by revaluation of contingent liabilities expenses of $0.1 million. Net changes in our operating assets and liabilities for the year ended December 31, 2020 consisted primarily of an increase in liabilities relating to operating leases of $1.4 million, and an increase in other account payables of $1.4 million, partially offset by an increase of $1.5 million in other receivables and a decrease in trade account payables of $0.8 million.

**Investing Activities**

During the year ended December 31, 2021, investing activities provided net cash of $16.2 million, mainly consisting of proceeds from withdrawal of short-term deposits of $19.8 million, partially offset by purchases of property and equipment of $3.7 million, primarily laboratory equipment and leasehold improvements.

During the year ended December 31, 2020, investing activities used net cash of $10.9 million, mainly consisting of net change in investment in short-term deposits of $9.9 million and purchases of property and equipment of $1.0 million, primarily laboratory equipment and leasehold improvements.

We have invested, and plan to continue to invest, our existing cash in short-term investments in accordance with our investment policy. These investments may include money market funds and investment securities consisting of U.S. Treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises. We use foreign exchange contracts (mainly option and forward contracts) to hedge balance sheet items from currency exposure. These foreign exchange contracts are not designated as hedging instruments for accounting purposes. In connection with these foreign exchange contracts, we recognize gains or losses that offset the revaluation of the balance sheet items also recorded under financial expenses, net. As of December 31, 2021, we had outstanding foreign exchange contracts in the amount of approximately $4.2 million with a fair value of $62 thousand. As of December 31, 2020, we had outstanding foreign exchange contracts in the amount of approximately $1.5 million, with a fair value of $90 thousand.

**Financing Activities**

During the year ended December 31, 2021, financing activities provided net cash of $37.3 million, consisting of $5.2 million due to issuance of Common Stock under the Sale Agreement, $17.7 million due to issuances of Common Stock under a registered direct offering, as described below, as well as investments by Maruho and the CF Foundation, $14.2 million proceeds from long-term debt and related to the Hercules Loan Agreement and $0.1 million from exercise of stock options.

During the year ended December 31, 2020, financing activities provided net cash provided of $134 thousand, consisting of $75 thousand due to the Business Combination, $98 thousand from issuance of Common Stock and $307 thousand from exercise of stock options.

**Contractual Obligations, Commitments and Contingencies**

Our contractual obligations and commitments relate primarily to our Hercules Loan Agreement, operating leases and non-cancelable purchase obligations under agreements with various research and development organizations and suppliers in the ordinary course of business. In September 2020, we entered into a lease agreement for new office and laboratory space in Ness Ziona, Israel. See note 8, “Leases” and note 12, “Long term Debt,” to our financial statements for further information.

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our certificate of incorporation and bylaws, as well as contractual indemnification agreements, we have potential indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

**Government Grants and Related Royalties**

The Government of Israel, through the IIA, encourages research and development projects by providing grants. We may receive grants from the IIA at the rates that range from 20% to 50% of the research and development expenses, as prescribed by the research committee of the IIA. Through December 31, 2021, we had received an aggregate of $5.6 million in the form of grants from the IIA. BiomX Ltd. was formed as an incubator company as part of the FutuRx incubator, and, until 2017, the majority of its funding was from IIA grants and funding by the incubator, which is supported by the IIA. We continued to apply for and receive IIA grants after we left the incubator. The requirements and restrictions for such grants are found in the Research Law. Under the Research Law, royalties of 3% to 3.5% on the revenue derived from sales of products or services developed in whole or in part using these IIA grants are payable to the Israeli government. We developed both of our platform technologies, at least in part, with funds from these grants, and, accordingly, we would be obligated to pay these royalties on sales of any of our product candidates that achieve regulatory approval.

Below is a description of our obligations in connection with the grants received from the IIA under the Research Law:

*Local Manufacturing Obligation*

As long as the manufacturing of our product candidates takes place in Israel and no technology funded with IIA grants is sold or out licensed to a non-Israeli entity, the maximum aggregate royalties paid generally would not exceed 100% of the grants made to us, plus annual interest equal to the 12-month LIBOR rate applicable to U.S. dollar deposits, as published on the first business day of each calendar year.

Under the terms of the Research Law, the products may be manufactured outside of Israel by us or by another entity only if prior approval is received from the IIA (such approval is not required for the transfer of up to 10% of the manufacturing capacity in the aggregate, in which case a notice must be provided to the IIA and not be objected to by the IIA within 30 days of such notice).

*Know-How Transfer Limitation*

The Research Law restricts the ability to transfer know-how funded by the IIA outside of Israel. Transfer of IIA funded know-how outside of Israel requires prior approval of the IIA and may be subject to payments to the IIA, calculated according to formulae provided under the Research Law. The redemption fee is subject to a cap of six times the total amount of the IIA grants, plus interest accrued thereon (i.e. the total liability to the IIA, including accrued interest, multiplied by six). If we wish to transfer IIA funded know-how, the terms for approval will be determined according to the nature of the transaction and the consideration paid to us in connection with such transfer.

Approval of transfer of IIA funded know-how to another Israeli company may be granted only if the recipient abides by the provisions of the Research Law and related regulations, including the restrictions on the transfer of know-how and manufacturing rights outside of Israel.

*Change of Control*

Any non-Israeli citizen, resident or entity that, among other things, (i) becomes a holder of 5% or more of our share capital or voting rights, (ii) is entitled to appoint our directors or our chief executive officer or (iii) serves as one of our directors or as our chief executive officer (including holders of 25% or more of the voting power, equity or the right to nominate directors in such direct holder, if applicable) is required to notify the IIA and undertake to comply with the rules and regulations applicable to the grant programs of the IIA, including the restrictions on transfer described above.

Approval to manufacture products outside of Israel or consent to the transfer of IIA funded know-how, if requested, is within the discretion of the IIA. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer IIA funded know-how or manufacturing out of Israel.

The consideration available to our shareholders in a future transaction involving the transfer outside of Israel of know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA.

As of December 31, 2021, no sales were generated and the balance of the principal and interest in respect of our commitments for future payments to the IIA totaled approximately $5.4 million. As part of funding our current and planned product development activities, we have submitted follow-up grant applications for new grants.

**Outlook**

We expect our expenses to remain substantially in the same level in connection with our ongoing activities. Our expenses will remain substantial and may also increase as we:

- continue the development of our product candidates;
- complete IND-enabling activities and prepare to initiate clinical trials for our product candidates;
- initiate additional clinical trials and preclinical studies for product candidates in our pipeline;
- seek to identify and develop or in-license or acquire additional product candidates and technologies;
- seek regulatory approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval;
- hire and retain additional personnel, such as clinical, quality control, commercial and scientific personnel; and
- expand our infrastructure and facilities to accommodate our growing employee base, including adding equipment and physical infrastructure to support our research and development.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements until at least the end of 2023. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we receive regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through public or private sales of our equity, including under the Sale Agreement or the additional investment under the CF Foundation agreement, loans, including the second and/or third tranches under the Hercules Loan Agreement, milestone payments, possibly additional grants from the IIA or other government or non-profit institutions and other outside funding sources. Our ability to raise additional capital in the equity and debt markets is dependent on a number of factors including, but not limited to, market volatility resulting from the COVID-19 pandemic, armed conflicts such as in Ukraine or other disruptions, market demand for our securities, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to the Company. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government and other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market by ourselves. For more information regarding the risks related to our outlook, see "*Risk Factors — Risks Related to Our Business, Technology and Industry.*"

**Foreign Exchange Contracts**

We entered into forward and option contracts to hedge against the risk of overall changes in future cash flow from payments of salaries and related expenses, as well as other expenses denominated in NIS. As of December 31, 2021 and 2020, we had outstanding foreign exchange contracts in the nominal amount of approximately $4.2 million and $1.5 million, respectively.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our consolidated financial statements are prepared in accordance with US GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

*Accrued research and development expenses*

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical and clinical trials; and
- subcontractors in connection with the manufacturing of materials for preclinical and clinical trials.

We measure the expense recognized based on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs and subcontractors that supply, conduct and manage preclinical studies, human clinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of certain milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in changes in estimates that increase or decrease amounts recognized in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

*Stock-Based Compensation*

We apply ASC 718-10, “Stock-Based Payment,” which requires the measurement and recognition of compensation expenses for all stock-based payment awards made to employees and directors, including employee stock options under our stock plans based on estimated fair values.

ASC 718-10 requires that we estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The fair value of the award is recognized as an expense over the requisite service periods in our Consolidated Statements of Operations. We recognize stock-based award forfeitures as they occur, rather than estimate by applying a forfeiture rate.

We recognize compensation expenses for the fair value of non-employee awards over the requisite service period of each award.

We estimate the fair value of stock options granted as equity awards using a Black-Scholes options pricing model. The option-pricing model requires a number of assumptions, of which the most significant are share price, expected volatility and the expected option term (the time from the grant date until the options are exercised or expire). We determine the fair value per share of the underlying stock by taking into consideration our most recent sales of stock. BiomX Ltd. has historically been a private company and lacks company-specific historical and implied volatility information of its stock. Expected volatility is estimated based on volatility of similar companies in the biotechnology sector. We have historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from governmental zero-coupon bonds with an equivalent term. The expected option term is calculated for options granted to employees and directors using the "simplified" method. Grants to non-employees are based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the options granted and the results of our operations.

*Intangible assets*

In-process research and development acquired in a business combination were recognized at fair value as of the acquisition date and subsequently accounted for as indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts.

We accounted for the acquisition of RondinX Ltd. using the acquisition method of accounting, which required us to estimate the fair values of the assets acquired and liabilities assumed. This included acquired in-process research and development and contingent consideration. Adjustments to the fair value of contingent consideration are recorded in earnings. On January 1, 2020, the in-process R&D efforts were completed. The Company had determined the useful life of the R&D assets for three years and began amortizing these assets accordingly in the financial statements.

We review these intangible assets at least annually for impairment, or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

**Emerging Growth Company Status**

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of our first registration statement filed under the Securities Act, or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our shares held by non-affiliates or we issue more than $1.0 billion of non-convertible debt securities over a three-year period.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to make disclosures under this Item.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and the notes thereto begin on page F-1 of this Annual Report.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, or CEO, and our Senior Vice President of Finance and Operations (our principal executive officer and principal financial officer, respectively), performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2021. Based on the aforementioned evaluation, our management has concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2021.

### Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting has been designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America.

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of our assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles in the United States of America, and that receipts and expenditures are being made only in accordance with authorization of our management and directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting on December 31, 2021. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework, in *Internal Control—Integrated Framework*. Based on that assessment under those criteria, management has determined that, as of December 31, 2021, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption for emerging growth companies provided in the JOBS Act.

### Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of fiscal year 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

On March 29, 2022, Mr. Paul Sekhri informed the Board of Directors of his resignation as a director of the Company, effective immediately. The resignation of Mr. Sekhri did not involve any disagreement with the Company, the Company's management or the Board of Directors.

## ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICITIONS THAT PREVENT INSPECTIONS

Not applicable.

## PART III

We intend to file a definitive proxy statement for our 2022 Annual General Meeting of Stockholders, or the 2022 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after December 31, 2021. Accordingly, certain information required by Part III has been omitted under General Instruction G (3) to Form 10-K. Only those sections of the 2022 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

**Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all directors, officers and employees. The Code of Business Conduct and Ethics is available on our website at www.biomx.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code to any director or executive officer, we will promptly disclose the nature of the amendment or waiver on our website.

**Other Information**

The remaining information required by this item will be included in our 2022 Proxy Statement, and such required information is incorporated herein by reference into this Annual Report.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in our 2022 Proxy Statement and is hereby incorporated by reference into this Annual Report.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

**Securities Authorized for Issuance Under Equity Compensation Plans**

We have two equity incentive plans, the 2015 Employee Stock Option Plan, or the 2015 Plan, and the Chardan Healthcare Acquisition Corp. 2019 Equity Incentive Plan, or the 2019 Plan. In October 2019, in connection with the Business Combination, we assumed the 2015 Plan with respect to each outstanding equity award thereunder. Although no shares of our Common Stock are available for future issuance under the 2015 Plan, the 2015 Plan will continue to govern outstanding awards granted thereunder. As of December 31, 2021, options to purchase 2,466,533 shares of our Common Stock remained outstanding under the 2015 Plan.

The 2019 Plan was adopted by the Board of Directors and approved by our stockholders in connection with the Business Combination. As of December 31, 2021, there were 216,036 shares of our Common Stock available for issuance under the 2019 Plan. The aggregate number of shares of our Common Stock available for issuance pursuant to the 2019 Plan automatically increases on January 1 of each year, for a period of not more than ten years, commencing on January 1, 2020 and ending on (and including) January 1, 2029, in an amount equal to 4% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year. Accordingly, on January 1, 2022, 1,190,129 additional shares of our Common Stock were made available for issuance pursuant to the 2019 Plan.

For additional information regarding the 2015 Plan and the 2019 Plan, as of December 31, 2021, please see Part II – Item 8 – Financial Statements and Supplemental Data – Notes to consolidated financial statements – Note 12B – Stock-Based Compensation.

| | Equity Compensation Plan Information December 31, 2021 | | |
|---|---|---|---|
| **Plan category** | **Number of securities to be issued upon exercise of outstanding options and restricted stock (a)** | **Weighted-average exercise price of outstanding options and restricted stock (b)** | **Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)** |
| Equity compensation plans approved by security holders | 1,618,012 | 6.64 | 216,036 |
| Equity compensation plans not approved by security holders | 2,466,533 | 2.19 | |
| Total | 4,084,545 | 3.95 | 216,036 |

The other information required by this item will be included under the "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our 2022 Proxy Statement and is hereby incorporated by reference into this Annual Report.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item will be included in our 2022 Proxy Statement and is hereby incorporated by reference into this Annual Report.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item will be included in our 2022 Proxy Statement and is hereby incorporated by reference into this Annual Report.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following are filed with this report:

(1) The financial statements listed on the Financial Statements' Table of Contents

(2) Not applicable

(b) Exhibits

The following exhibits are filed as part of this Annual Report or are incorporated by reference.

### EXHIBIT INDEX

| Exhibit | Description |
|---|---|
| 3.1 | Composite Copy of Amended and Restated Certificate of Incorporation of the Company, effective on December 11, 2018, as amended to date. (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed by the Company on August 13, 2020) |
| 3.2 | Amended and Restated Bylaws of the Company, effective as of October 28, 2019 (Incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019) |
| 4.1 | Description of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (Incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K filed by the Company on March 31, 2021) |
| 4.2 | Specimen Unit Certificate (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed by the Company on December 4, 2018) |
| 4.3 | Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed by the Company on December 4, 2018) |
| 4.4 | Specimen Warrant Certificate (Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed by the Company on December 4, 2018) |
| 4.5 | Warrant Agreement, dated December 13, 2018 between Continental Stock Transfer & Trust Company and the Company (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed by the Company on December 18, 2018) |
| 4.6 | Form of Warrant. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed by the Company on July 26, 2021) |
| 10.1 | Registration Rights Agreement dated October 28, 2019 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019) |
| 10.2** | Form of Indemnification Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed by the Company on November 12, 2020) |
| 10.3* | Research and License Agreement, dated June 22, 2015, between BiomX Ltd. and Yeda Research and Development Company Limited, as amended (Incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019) |
| 10.4* | Exclusive Patent License Agreement, dated December 15, 2017, among BiomX Ltd., Keio University and JSR Corporation, as amended (Incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019) |

| | |
|---|---|
| 10.5* | Exclusive Patent License Agreement, dated April 22, 2019, among BiomX Ltd., Keio University and JSR Corporation (Incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019) |
| 10.6** | Chardan Healthcare Acquisition Corp. 2019 Equity Incentive Plan (Incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019) |
| 10.7** | 2015 Employee Stock Option Plan for Key Employees of BiomX Ltd., as amended (Incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8 filed by the Company on January 2, 2020) |
| 10.8 | Registration Rights Agreement, dated December 13, 2018, among the Company and the initial stockholders and Chardan Capital Markets, LLC. (Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed by the Company on December 18, 2018) |
| 10.9** | Form of Non-Qualified Stock Option Agreement (U.S. Awards to Non-Executives) (Incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K filed by the Company on March 26, 2020) |
| 10.10** | Form of Non-Qualified Stock Option Agreement (U.S. Awards to Executive Officers) (Incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed by the Company on March 26, 2020) |
| 10.11** | Form of Option Agreement (Israeli Awards) (Incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed by the Company on March 26, 2020) |
| 10.12* | An addendum to a lease agreement dated from May 25, 2017, dated September 7, 2020 by and among AFI Assets Ltd., AF – SHAR Ltd., WIS and BiomX Ltd. (translated from Hebrew) (Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed by the Company on March 31, 2021) |
| 10.13* | A lease agreement dated September 7, 2020 by and among AFI Assets Ltd., AF – SHAR Ltd., WIS, Nova Measuring Systems Ltd. and BiomX Ltd. (translated from Hebrew) (Incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed by the Company on March 31, 2021) |
| 10.14 | Open Market Sale Agreement[SM], dated December 4, 2020, between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed by the Company on December 4, 2020). |
| 10.15 | Loan and Security Agreement dated August 16, 2021 by and among BiomX, Inc., BiomX Ltd., RondinX Ltd. and Hercules Capital, Inc. (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed by the Company on August 16, 2021) |
| 21.1 | Subsidiaries of Company (Incorporated by reference to Exhibit 21.1 to the Company's Current Report on Form 8-K filed by the Company on November 1, 2019) |
| 23.1 | Consent of Brightman Almagor Zohar & Co., independent registered public accounting firm |
| 23.2 | Consent of Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited |
| 31.1 | Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a). |
| 31.2 | Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a). |
| 32*** | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350. |
| 101.INS | Inline XBRL Instance Document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

* Portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

** Indicates a management contract or a compensatory plan or agreement.

*** Furnished herewith

**Item 16. Form 10-K Summary**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOMX INC.

Dated: March 30, 2022

By: /s/ Jonathan Solomon
Name: Jonathan Solomon
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Dr. Russell Greig<br>Dr. Russell Greig | Chairman of the Board of Directors | March 30, 2022 |
| /s/ Jonathan Solomon<br>Jonathan Solomon | Chief Executive Officer<br>(Principal Executive Officer) and Director | March 30, 2022 |
| /s/ Marina Wolfson<br>Marina Wolfson | Senior Vice President of Finance and Operations<br>(Principal Financial Officer and Principal Accounting Officer) | March 30, 2022 |
| /s/ Dr. Gbola Amusa<br>Dr. Gbola Amusa | Director | March 30, 2022 |
| /s/ Jonas Grossman<br>Jonas Grossman | Director | March 30, 2022 |
| /s/ Dr. Alan Moses<br>Dr. Alan Moses | Director | March 30, 2022 |
| /s/ Lynne Sullivan<br>Lynne Sullivan | Director | March 30, 2022 |

**BIOMX INC.**

**CONSOLIDATED FINANCIAL STATEMENTS**
**DECEMBER 31, 2021**

**BIOMX INC.**

**CONSOLIDATED FINANCIAL STATEMENTS**
**DECEMBER 31, 2021**

**CONTENTS**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and stockholders of BiomX Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheet of BiomX Inc. and its subsidiaries (the "Company") as of December 31, 2021, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the year then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited
Tel-Aviv, Israel

March 30, 2022

We have served as the Company's auditor since 2021.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**To the Stockholders and Board of Directors of BiomX Inc.**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of BiomX Inc. (the "Company") as of December 31, 2020, the related consolidated statements of operations, changes in stockholders' equity and cash flows for year ended December 31, 2020, and the related notes (collectively referred to as the "financial statements").

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and the results of its operations and its cash flows for the year ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
March 31, 2021

We have served as the Company's auditor since 2015.

In October 2021 we became the predecessor auditor.

**BIOMX INC.**
CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)

| | Note | As of December 31, 2021 | 2020 |
|---|---|---|---|
| **ASSETS** | | | |
| **Current assets** | | | |
| Cash and cash equivalents | | 62,099 | 36,477 |
| Restricted cash | | 996 | 763 |
| Short-term deposits | 3 | - | 19,851 |
| Other current assets | 4 | 3,543 | 3,576 |
| Total current assets | | 66,638 | 60,667 |
| **Non-current assets** | | | |
| Operating lease right-of-use assets | 8 | 4,139 | 4,430 |
| Property and equipment, net | 5 | 5,694 | 2,228 |
| Intangible assets, net | 7 | 1,519 | 3,038 |
| Total non-current assets | | 11,352 | 9,696 |
| | | 77,990 | 70,363 |

**The accompanying Notes are an integral part of the consolidated financial statements.**

**BIOMX INC.**
CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)

| | Note | As of December 31, 2021 | 2020 |
|---|---|---|---|
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | | |
| **Current liabilities** | | | |
| Trade account payables | | 2,795 | 2,320 |
| Current portion of lease liabilities | 8 | 819 | 863 |
| Contract liability | | 1,976 | - |
| Other account payables | 9 | 5,453 | 3,978 |
| Total current liabilities | | 11,043 | 7,161 |
| **Non-current liabilities** | | | |
| Long-term debt | 12 | 14,410 | - |
| Operating lease liabilities, net of current portion | 8 | 4,787 | 5,032 |
| Other liabilities | 6, 11 | 215 | 701 |
| Total non-current liabilities | | 19,412 | 5,733 |
| **Commitments and Collaborations** | 11 | | |
| **Stockholders' equity** | | | |
| Preferred Stock, $0.0001 par value; Authorized - 1,000,000 shares as of December 31, 2021 and December 31, 2020. No shares issued and outstanding as of December 31, 2021 and December 31, 2020. | | - | - |
| Common stock, $0.0001 par value ("Common Stock"); Authorized - 60,000,000 shares as of December 31, 2021 and 2020. Issued - 29,753,238 and 23,270,337 as of December 31,2021 and 2020, respectively. Outstanding - 29,747,538 and 23,264,637 as of December 31, 2021 and 2020, respectively. | 13 | 2 | 2 |
| Additional paid in capital | | 156,017 | 129,725 |
| Accumulated deficit | | (108,484) | (72,258) |
| Total Stockholders' equity | | 47,535 | 57,469 |
| | | 77,990 | 70,363 |

**The accompanying Notes are an integral part of the consolidated financial statements.**

**BIOMX INC.**

CONSOLIDATED STATEMENTS OF OPERATIONS

(USD in thousands, except share and per share data)

| | Note | Year ended December 31, 2021 | 2020 |
|---|---|---|---|
| Research and development ("R&D") expenses, net | 14 | 22,676 | 19,417 |
| Amortization of intangible assets | | 1,519 | 1,518 |
| General and administrative expenses | 15 | 11,267 | 9,323 |
| **Operating loss** | | 35,462 | 30,258 |
| Interest expenses | | 699 | - |
| Financial income, net | 16 | (2) | (172) |
| **Loss before tax** | | 36,159 | 30,086 |
| Tax expenses | 17 | 67 | - |
| **Net Loss** | | 36,226 | 30,086 |
| Basic and diluted loss per share of Common Stock | 18 | 1.39 | 1.30 |
| Weighted average number of shares of Common Stock outstanding, basic and diluted | | 26,007,947 | 23,062,216 |

**The accompanying Notes are an integral part of the consolidated financial statements.**

**BIOMX INC.**

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(USD in thousands, except share and per share data)

| | Common stock | | Additional paid in | Accumulated | Total Stockholder' |
|---|---|---|---|---|---|
| | Shares | Amount | capital | deficit | equity |
| **Balance as of January 1, 2020** | 22,862,835 | 2 | 126,626 | (42,172) | 84,456 |
| Exercise of stock options | 391,626 | - | 307 | - | 307 |
| Issuance of Common Stock under Open Market Sales Agreement, net of $158 issuance costs (***) | 10,176 | - | (98) | - | (98) |
| Stock-based compensation expenses | - | - | 2,890 | - | 2,890 |
| Net loss | - | - | - | (30,086) | (30,086) |
| **Balance as of December 31, 2020** | 23,264,637 | 2 | 129,725 | (72,258) | 57,469 |
| Exercise of stock options | 84,239 | * | 130 | - | 130 |
| Exercise of warrants (**) | 362,383 | * | - | - | - |
| Issuance of Common Stock under Open Market Sales Agreement, net of $158 issuance costs (***) | 743,964 | * | 5,188 | - | 5,188 |
| Issuance of Common Stock under Securities Purchase Agreement ("SPA"), net of $1,235 issuance costs (***) | 3,750,000 | * | 13,765 | - | 13,765 |
| Issuance of Common Stock under Stock Purchase Agreement with Maruho, net of $52 issuance costs (***) | 375,000 | * | 972 | - | 972 |
| Issuance of Common Stock under Securities Purchase Agreement with CF Foundation (***) | 1,167,315 | * | 3,000 | - | 3,000 |
| Stock-based compensation expenses | - | - | 3,237 | - | 3,237 |
| Net loss | - | - | - | (36,226) | (36,226) |
| **Balance as of December 31, 2021** | 29,747,538 | 2 | 156,017 | (108,484) | 47,535 |

(*) Less than $1.

(**) See Note 13B(1).

(***) See Note 13A.

**The accompanying Notes are an integral part of the consolidated financial statements.**

**BIOMX INC.**

CONSOLIDATED STATEMENTS OF CASH FLOWS

(USD in thousands, except share and per share data)

| | Year ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **CASH FLOWS – OPERATING ACTIVITIES** | | |
| Net loss | (36,226) | (30,086) |
| | | |
| Adjustments required to reconcile net loss to cash flows used in operating activities | | |
| Depreciation and amortization | 2,565 | 2,180 |
| Stock-based compensation | 3,237 | 2,890 |
| Amortization of debt issuance costs | 185 | - |
| Finance expense, net | 25 | - |
| Changes in other liabilities | (486) | 116 |
| Loss from sale of property and equipment | 24 | - |
| | | |
| Changes in operating assets and liabilities: | | |
| Other current assets | 33 | (1,503) |
| Trade account payables | 427 | (858) |
| Contract liability | 1,976 | - |
| Other account payables | 665 | 1,382 |
| Net change in operating leases | 2 | 1,382 |
| Related parties | - | 50 |
| **Net cash used in operating activities** | (27,573) | (24,447) |
| | | |
| **CASH FLOWS – INVESTING ACTIVITIES** | | |
| Investment in short-term deposits | - | (49,780) |
| Proceeds from short -term deposits | 19,851 | 39,932 |
| Purchase of property and equipment | (3,682) | (1,009) |
| Proceeds from sale of property and equipment | 4 | - |
| **Net cash provided by (used in) investing activities** | 16,173 | (10,857) |
| | | |
| **CASH FLOWS – FINANCING ACTIVITIES** | | |
| Issuance of Common Stock under Open Market Sales Agreement, net of issuance costs | 5,188 | (98) |
| Issuance of Common Stock under registered direct offering, net of issuance costs | 17,737 | - |
| Proceeds from long-term debt, net of issuance costs | 14,225 | - |
| Outflows in connection with current assets and liabilities acquired in Recapitalization Transaction | - | (75) |
| Exercise of stock options | 130 | 307 |
| **Net cash provided by financing activities** | 37,280 | 134 |
| | | |
| **Increase (decrease) in cash and cash equivalents and restricted cash** | 25,880 | (35,170) |
| | | |
| **Effect of exchange rate changes on cash and cash equivalents and restricted cash** | (25) | - |
| | | |
| **Cash and cash equivalents and restricted cash at the beginning of the year** | 37,240 | 72,410 |
| | | |
| **Cash and cash equivalents and restricted cash at the end of the year** | 63,095 | 37,240 |

**The accompanying Notes are an integral part of the consolidated financial statements.**

**BIOMX INC.**
CONSOLIDATED STATEMENTS OF CASH FLOWS
(USD in thousands, except share and per share data)

| | Year ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:** | | |
| Cash paid for interest | 399 | - |
| Taxes paid | 67 | - |
| **SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:** | | |
| Property and equipment purchases included in accounts payable and other payables | 858 | - |
| Right-of-use assets obtained in exchange for new operation lease liabilities | 95 | 4,547 |

**The accompanying Notes are an integral part of the consolidated financial statements.**

## NOTE 1 - GENERAL

### A. General information:

BiomX Inc., (individually, and together with its subsidiaries, BiomX Ltd. and RondinX Ltd., the "Company" or "BiomX") was incorporated as a blank check company on November 1, 2017, under the laws of the state of Delaware, for the purpose of entering into a merger, stock exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses or entities.

On July 16, 2019, the Company entered into a merger agreement with BiomX Ltd. ("BiomX Israel"), a company incorporated under the laws of Israel, CHAC Merger Sub Ltd. ("Merger Sub") and Shareholder Representative Services LLC, as amended on October 11, 2019, pursuant to which, among other things, BiomX Israel merged with Merger Sub, with BiomX Israel being the surviving entity in accordance with the Israeli Companies Law, 5759-1999, as a wholly owned direct subsidiary of BiomX Inc.

On October 28, 2019, the Company consummated the acquisition of 100% of the outstanding shares of BiomX Israel (the "Recapitalization Transaction"). Pursuant to the aforementioned merger agreement, in exchange for all of the outstanding shares of BiomX Israel, the Company issued to the shareholders of BiomX Israel a total of 15,069,058 shares of the Company's Common Stock representing approximately 65% of the total shares issued and outstanding after giving effect to the Recapitalization Transaction. As a result of the Recapitalization Transaction, BiomX Israel became a wholly owned subsidiary of the Company. As the shareholders of BiomX Israel received the largest ownership interest in the Company, BiomX Israel was determined to be the "accounting acquirer" in the Recapitalization Transaction.

Following the Recapitalization Transaction, the Company retained $60,100 held in a trust account, after redemptions of shares held by certain shareholders in connection with the initial public offering of Chardan Healthcare Acquisition Corp. (refer to Note 13A).

The Company's shares of Common Stock, units, and warrants are traded on the NYSE American under the symbols PHGE, PHGE.U, and PHGE.WS, respectively.

On February 6, 2020, the Company's Common Stock also began trading on the Tel-Aviv Stock Exchange.

BiomX is developing both natural and engineered phage cocktails designed to target and destroy harmful bacteria in chronic diseases, such as cystic fibrosis, atopic dermatitis, inflammatory bowel disease and colorectal cancer. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets. The Company's
headquarters are located in Ness Ziona, Israel

### B. COVID-19

On March 12, 2020, the World Health Organization declared COVID-19 a global pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries have imposed unprecedented restrictions on travel, mandatory business closures and other measures designed to mitigate the spread, leading to a substantial reduction in economic activities in countries around the world, resulting in certain disruptions to our business throughout 2020 and in 2021.

In response to the pandemic, the Company implemented the mandatory as well as recommended measures to safeguard the health and safety of its employees and clinical trial participants, and the continuity of its business operations, including social distancing in its offices, a work from home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel, and the Company expects to continue to take actions as may be required or recommended by government authorities or as the Company determines are in the best interests of its employees, clinical trial participants and others in light of COVID-19. As of December 31, 2021, COVID-19 has not had a material impact on the Company's results of operations. However, uncertainty remains as to the potential impact of COVID-19 on its future research and development activities and the potential for a material impact on the Company increases the longer the virus impacts certain aspects of economic activity around the world. The full extent to which COVID-19 will directly or indirectly impact the Company's business, results of operations and financial condition, including the Company's ability to fulfill its clinical trial enrollment needs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets, the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, the effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. During the second quarter of 2020, the Company updated its guidance on the timing of certain clinical milestones partly due to the health and safety precautions the Company had taken and challenges it continues to face in clinical trial enrollment due to COVID-19. It is not currently possible to predict how long the pandemic will last, what the long-term global effects will be, or the time that it will take for economic activity to return to pre-pandemic levels, and the Company does not yet know the full impact on its business and operations. The Company will continue to monitor COVID-19 closely and follow health and safety guidelines as they evolve.

**NOTE 1 - GENERAL (Cont.)**

**C. Risk factors:**

To date, the Company has not generated revenue from its operations. Based on the Company's current cash and commitments, management believes that the Company's current cash and cash equivalents are sufficient to fund its operations for more than 12 months from the date of issuance of these consolidated financial statements and sufficient to fund its operations necessary to continue development activities.

Consistent with its continuing research and development activities, the Company expects to continue to incur additional losses for the foreseeable future. The Company plans to continue to fund its current operations, as well as other development activities relating to additional product candidates, through future issuances of debt and/or equity securities, loans and possibly additional grants from the Israel Innovation Authority ("IIA") and other government institutions. The Company's ability to raise additional capital in the equity and debt markets is dependent on a number of factors including, but not limited to, the market demand for the Company's Common Stock, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to it.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES**

The significant accounting policies applied in the preparation of the financial statements on a consistent basis, are as follows, except for the adoption of new accounting standards:

**A. Basis of presentation and principles of consolidation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries, BiomX Israel and RondinX Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

**B. Use of estimates in the preparation of financial statements**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities in the financial statements and the amounts of expenses during the reported years. Actual results could differ from those estimates.

**C. Reclassification**

Certain prior year amounts have been reclassified to conform to the current year presentation.

**D. Functional currency and foreign currency translation**

The functional currency of the Company is the U.S. dollar ("dollar") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future.

Transactions and balances denominated in dollars are presented at their original amounts.

Transactions and balances denominated in foreign currencies have been re-measured to dollars in accordance with the provisions of ASC 830-10, "Foreign Currency Matters."

All transaction gains and losses from remeasurement of monetary balance sheet items denominated in foreign currencies are reflected in the statements of operations as financial income or expenses, as appropriate.

**E. Cash and cash equivalents**

The Company considers cash equivalents to be all short-term, highly liquid investments, which include money market instruments, that are not restricted as to withdrawal or use, and short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

(USD in thousands, except share and per share data)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

**F. Concentrations of credit risk**

Financial instruments which potentially subject us to credit risk consist primarily of cash, cash equivalents, and short-term deposits. These amounts at times may exceed federally insured limits. We have not experienced any credit losses in such accounts and do not believe we are exposed to any significant credit risk on these funds. Refer to Note 2K.

**G. Property and equipment**

Property and equipment are presented at cost less accumulated depreciation. Depreciation is calculated based on the straight-line method over the estimated useful lives of the related assets or terms of the related leases, as follows:

| | Estimated Useful Lives |
|---|---|
| Laboratory equipment | 7 years |
| Computers and software | 3 years |
| Equipment and furniture | 15 years |
| Leasehold improvements | Shorter of lease term or useful life |

**H. Intangible assets**

Intangible research and development assets acquired in a business combination are recognized at fair value as of the acquisition date and capitalized as an indefinite life intangible asset until the related research and development efforts are either completed or abandoned. In the reporting periods where they are treated as indefinite life intangible assets, they are not amortized but rather are monitored for triggering events and tested for impairment. Upon completion of the related research and development efforts, management determines the useful life of the intangible assets and amortizes them accordingly.

**I. Long-lived assets**

In accordance with ASC 360-10, "Impairment and Disposal of Long-Lived Assets", management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable based on estimated future undiscounted cash flows. If so indicated, an impairment loss would be recognized for the difference between the carrying amount of the asset and its fair value. For the years ended December 31, 2021 and 2020, no impairment expenses were recorded.

**J. Income taxes**

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax basis of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all the deferred tax assets will not be realized. As of December 31, 2021 and 2020, the Company had a full valuation allowance against deferred tax assets.

The Company is subject to the provisions of ASC 740-10-25, "Income Taxes" ("ASC 740"). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. On a yearly basis, the Company undergoes a process to evaluate whether income tax accruals are in accordance with ASC 740 guidance on uncertain tax positions. The Company has not recorded any liability for uncertain tax positions for the years ended December 31, 2021 and 2020.

**K. Derivative activity**

The Company uses foreign exchange contracts (option and forward contracts) to hedge cash flows from currency exposure. These foreign exchange contracts are not designated as hedging instruments for accounting purposes. In connection with these foreign exchange contracts, the Company recognizes gains or losses that offset the revaluation of the cash flows also recorded under financial expenses (income), net in the consolidated statements of operations. As of December 31, 2021, the Company had outstanding foreign exchange contracts for the exchange of U.S. dollars ("USD") to NIS in the amount of approximately $4,180 with a fair value of $62. As of December 31, 2020, the Company had outstanding foreign exchange contracts for the exchange of USD to NIS in the amount of approximately $1,555 with a fair value of $90.

(USD in thousands, except share and per share data)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

**L. Fair value of financial instruments**

The Company accounts for financial instruments in accordance with ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"). ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 – Quoted prices in non-active markets or in active markets for similar assets or liabilities, observable inputs other than quoted prices, and inputs that are not directly observable but are corroborated by observable market data.

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

There were no changes in the fair value hierarchy levelling during the years ended December 31, 2021 and 2020.

The following table summarizes the fair value of our financial assets and liabilities that were accounted for at fair value on a recurring basis, by level within the fair value hierarchy:

| | December 31, 2021 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Fair Value** |
| Assets: | | | | |
| Cash equivalents: | | | | |
| Money market funds | 30,007 | - | - | 30,007 |
| Foreign exchange contracts receivable | | 62 | | 62 |
| | **30,007** | **62** | **-** | **30,069** |
| Liabilities: | | | | |
| Contingent consideration | - | - | 175 | 175 |
| | - | - | **175** | **175** |

| | December 31, 2020 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Fair Value** |
| Assets: | | | | |
| Cash equivalents: | | | | |
| Money market funds | 30,000 | - | - | 30,000 |
| Foreign exchange contracts receivable | | 90 | | 90 |
| | **30,000** | **90** | **-** | **30,090** |
| Liabilities: | | | | |
| Contingent consideration | - | - | 83 | 83 |
| | - | - | **83** | **83** |

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

**L. Fair value of financial instruments (Cont.)**

Refer to Note 13A regarding the fair value of the financial instrument that resulted from the CFF agreement.

Financial instruments with carrying values approximating fair value include cash and cash equivalents, restricted cash, short-term deposits, other current assets, trade accounts payable and other current liabilities, due to their short-term nature.

The Company determined the fair value of the liabilities for the contingent consideration based on a probability discounted cash flow analysis. This fair value measurement is based on significant unobservable inputs in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent consideration is based on several factors, such as: the attainment of future clinical, developmental, regulatory, commercial and strategic milestones relating to product candidates for treatment of primary sclerosing cholangitis. The discount rate applied ranged from 0.37% to 1.26%. The contingent consideration is evaluated quarterly, or more frequently, if circumstances dictate. Changes in the fair value of contingent consideration are recorded in consolidated statements of operations. Significant changes in unobservable inputs, mainly the probability of success and cash flows projected, could result in material changes to the contingent consideration liability. Changes in contingent consideration for the years ended December 31, 2021 and 2020 resulted mainly from revaluation.

**M. Defined contribution plans**

Under Israeli employment laws, employees of BiomX Israel are included under Section 14 of the Severance Compensation Act, 1963 ("Section 14") for a portion of their salaries. Pursuant to Section 14, these employees are entitled to monthly deposits made by the Company on their behalf with insurance companies.

Payments in accordance with Section 14 release the Company from any future severance payments (under the Israeli Severance Compensation Act, 1963) with respect of those employees. The aforementioned deposits are not recorded as an asset on the Company's balance sheet, and there is no liability recorded as the Company does not have a future obligation to make any additional payments. The Company's contributions to the defined contribution plans are charged to the consolidated statements of operations as and when the services are received from the Company's employees. Total expenses with respect to these contributions were $689 and $567 for the years ended December 31, 2021 and 2020, respectively.

For U.S. employees the Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees of BiomX Inc in the U.S. who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis.

The Company has not elected to match any of the employee's deferral. During the years ended December 31, 2021 and 2020 the Company did not record any expenses for 401(k) match contributions.

**N. Financial instruments**

When the Company issues freestanding instruments, it first analyzes the provisions of ASC 480, "Distinguishing Liabilities From Equity" ("ASC 480") in order to determine whether the instrument should be classified as a liability, with subsequent changes in fair value recognized in the consolidated statements of operations in each period. If the instrument is not within the scope of ASC 480, the Company further analyzes the provisions of ASC 815-10 in order to determine whether the instrument is considered indexed to the entity's own stock, and qualifies for classification within equity. All warrants issued by the Company are classified within stockholders' equity as "Additional paid-in capital". Equity classification is permitted when warrants are indexed to the Company's own shares and meet the classification requirements for stockholders' equity classification of ASC 815-40, Accounting Standards Codification ("ASC 815-40").

**O. Collaborative arrangements**

The Company entered into collaborative arrangements with partners that fall under the scope of Topic 808, "Collaborative Arrangements" ("ASC 808"). While these arrangements are in the scope of ASC 808, the Company may analogize to ASC 606 for some aspects of the arrangements. The Company analogizes to ASC 606, "Revenue from Contracts with Customers" ("ASC 606") for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of its ongoing major or central operations.

The terms of the Company's collaborative arrangements typically include reimbursements or cost-sharing of R&D expenses. Each of these payments results in an offset against R&D expenses.

Under certain collaborative arrangements, the Company has been reimbursed for a portion of its R&D expenses or participates in the cost-sharing of such R&D expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of R&D expense in the Company's consolidated statements of operations, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

**P. Research and development costs**

Research and development costs are charged to statements of operations as incurred. Royalty-bearing grants from the IIA are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred and applied as a deduction from research and development expenses.

**Q. Basic and diluted loss per share**

Basic loss per share is computed by dividing net loss by the weighted average number of shares of Common Stock outstanding during the year. Diluted loss per share is computed by dividing net loss by the weighted average number of shares of Common Stock outstanding during the year, plus the number of shares of Common Stock that would have been outstanding if all potentially dilutive shares of Common Stock had been issued, using the treasury stock method, in accordance with ASC 260-10 "Earnings per Share." Potentially dilutive shares of Common Stock were excluded from the calculation of diluted loss per share for all periods presented due to their anti-dilutive effect due to losses in each period.

**R. Stock compensation plans**

The Company applies ASC 718-10, "Stock-Based Payment," ("ASC 718-10") which requires the measurement and recognition of compensation expenses for all stock-based payment awards made to employees and directors including employee stock options under the Company's stock plans based on estimated fair values.

ASC 718-10 requires companies to estimate the fair value of stock-based payment awards granted to employees and non-employees on the date of grant using an option-pricing model. The fair value of the award is recognized as an expense over the requisite service periods in the Company's statements of operations using the graded vesting method. The Company accounts for share-based payment awards classified as equity awards. The Company recognizes stock-based award forfeitures as they occur rather than estimate by applying a forfeiture rate.

All issuances of stock options or other equity instruments to non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

**R. Stock compensation plans (Cont.)**

The Company estimates the fair value of stock options granted as equity awards using a Black-Scholes option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are share price, expected volatility and the expected option term (the time from the grant date until the options are exercised or expire). Expected volatility is estimated based on volatility of similar companies in the technology sector. The Company has historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from governmental zero-coupon bonds with an equivalent term. The expected option term is calculated for options granted to employees and directors using the "simplified" method. Grants to non-employees are based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the options granted and the results of operations of the Company.

**S. Leases**

Under Accounting Standards Update, "Leases" ("ASC 842"), the Company determines if an arrangement is a lease at inception. Upon initial recognition, the Company recognizes a liability at the present value of the lease payments to be made over the lease term, and concurrently recognizes a right-of-use asset at the same amount of the liability, adjusted for any prepaid or accrued lease payments, plus initial direct costs incurred in respect of the lease. The Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of the lease payments. The subsequent measurement depends on whether the lease is classified as a finance lease or an operating lease. During the reporting periods, the Company has only operating leases. Lease terms include options to extend the lease when it is reasonably certain that the Company will exercise that option. Lease expenses for operating leases are recognized on a straight-line basis over the lease term.

The Company has made a policy election not to capitalize leases with a term of 12 months or less.

In accordance with ASC 360-10, management reviews operating lease assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable based on estimated future undiscounted cash flows. If so indicated, an impairment loss would be recognized for the difference between the carrying amount of the asset and its fair value.

**T. Treasury Stock**

Treasury shares are presented as a reduction of equity, at their cost to the Company.

**U. Recent Accounting Standards**

As an "emerging growth company," the Jumpstart Our Business Startups Act ("JOBS Act") allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected not to use this extended transition period under the JOBS Act. The adoption dates referenced below reflects this election.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

**U. Recent Accounting Standards (Cont.)**

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, "Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments." This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for smaller reporting companies (as defined by the rules under the Securities Exchange Act of 1934, as amended) for the fiscal year beginning on January 1, 2023, including interim periods within that year. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, "Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting For Convertible Instruments and Contracts in an Entity's Own Equity". The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for annual and interim periods beginning after December 15, 2021, and early adoption was permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company expects to apply modified retrospective basis adoption of this guidance, which will not have a significant impact on the Company's consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, "Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation— Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options". The guidance is effective for the Company on January 1, 2022. The Company expects that this guidance, will not have a significant impact on the Company's consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, "Business Combinations (Topic 805), Accounting for Contract Assets and Contract Liabilities from Contracts with Customers", which requires contract assets and contract liabilities acquired in a business combination to be recognized and measured by the acquirer on the acquisition date in accordance with ASC 606. The guidance will result in the acquirer recognizing contract assets and contract liabilities at the same amounts recorded by the acquiree. The guidance should be applied prospectively to acquisitions occurring on or after the effective date. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted, including in interim periods, for any financial statements that have not yet been issued. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10, "Government Assistance (Topic 832)", which requires annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity's financial statements. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2021. The Company expects that this guidance, will not have a significant impact on the Company's consolidated financial statements.

**NOTE 3 - SHORT-TERM DEPOSITS**

Short-term deposits represent time deposits placed with banks with original maturities of greater than three months but less than one year. Interest earned is recorded as finance income, net in the consolidated statements of operations during the years for which the Company held short-term deposits.

As of December 31, 2021, the Company had no deposits. As of December 31, 2020, the Company had deposits in USD at Leumi Bank (Israel) and BHI USA that bore fixed annual interest between 0.51% and 1.58%.

(USD in thousands, except share and per share data)

## NOTE 4 - OTHER CURRENT ASSETS

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Government institutions | 337 | 276 |
| Prepaid insurance | 2,149 | 2,055 |
| Other prepaid expenses | 99 | 29 |
| Lease incentive | - | 1,075 |
| Grants receivables | 888 | - |
| Other | 70 | 141 |
| | 3,543 | 3,576 |

## NOTE 5 - PROPERTY AND EQUIPMENT, NET

Composition of assets, grouped by major classifications, is as follows:

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Computers and software | 567 | 483 |
| Laboratory equipment | 3,752 | 2,357 |
| Equipment and furniture | 154 | 120 |
| Leasehold improvements | 2,987 | 587 |
| Accumulated depreciation | (1,766) | (1,319) |
| | 5,694 | 2,228 |

Substantially all the Company's non-current assets are concentrated in Israel.

Depreciation expenses were $1,046, and $662 in the years ended December 31, 2021 and 2020, respectively.

## NOTE 6 - ACQUISITION OF SUBSIDIARY

In November 2017, BiomX Israel signed a share purchase agreement with the shareholders of RondinX Ltd. In accordance with the share purchase agreement, BiomX Israel acquired 100% control and ownership of RondinX Ltd. for consideration valued at $4,500. The consideration included the issuance of 250,023 Preferred A Shares, the issuance of warrants to purchase an aggregate of 4,380 Series A-1 preferred shares, and additional contingent consideration. The contingent consideration is based on the attainment of future clinical, developmental, regulatory, commercial and strategic milestones relating to product candidates for treatment of primary sclerosing cholangitis or entry into qualifying collaboration agreements with certain third parties and may require the Company to issue 567,729 shares of Common Stock upon the attainment of certain milestones, as well as make future cash payments and/or issue additional shares of the most senior class of the Company's shares of Common Stock authorized or outstanding as of the time the payment is due, or a combination of both, up to $32,000 within ten years from the closing of the agreement. The Company has the discretion of determining whether milestone payments will be made in cash or by issuance of shares of Common Stock.

The contingent consideration is accounted for at fair value (level 3). There were no changes in the fair value hierarchy levelling during the years ended December 31, 2021 and December 31, 2020. Refer to Note 2K.

The consolidated financial statements as of December 31, 2021 and 2020 include a liability with respect to this agreement in the amount of $175 and $83, respectively, recorded as other liabilities.

## NOTE 7 - INTANGILE ASSETS, NET

Intangible assets acquired in the RondinX Ltd. acquisition (see Note 6) were determined to be in-process research and development ("R&D"). In accordance with ASC 350-30-35-17A, R&D assets acquired in a business combination are considered an indefinite-lived intangible asset until completion or abandonment of the associated R&D efforts. On January 1, 2020, the in-process R&D efforts were completed. The Company had determined the useful life of the R&D assets for three years and began amortizing these assets accordingly. Amortization expenses recorded in the consolidated statements of operations were $1,519 and $1,518 for the years ended December 31, 2021 and 2020, respectively. Based on management's analysis, there was no indicators for impairment for the years ended December 31, 2021 and 2020.

## NOTE 8 - LEASES

In May 2017, BiomX Israel entered into a lease agreement for office space in Ness Ziona, Israel. The agreement is for five years beginning on June 1, 2017 with an option to extend for an additional five years. Monthly lease payments under the agreement are approximately $18.

In September 2019, BiomX Israel entered into an additional lease agreement for office space in Ness Ziona, Israel. The agreement is for five years beginning on September 8, 2019 with an option to extend for an additional three years. The option was not accounted for as part of the lease, given its low probability of being exercised. Monthly lease payments under the agreement are approximately $12.

In September 2020, BiomX Israel entered into a third lease agreement for office space in Ness Ziona, Israel for five years beginning on September 1, 2020, with an option to extend for an additional period until November 30, 2030. This agreement supersedes the abovementioned May 2017 and September 2019 lease agreements and sets the prior lease agreements' end date to March 31, 2021. Monthly lease payments under the new lease agreement are approximately $50. As part of the agreement, BiomX Israel was exempted from monthly payments under the new agreement until January 15, 2021. In addition, the lessor reimbursed BiomX Israel for costs incurred for leasehold improvements by a pre-defined amount. BiomX Israel will pay back the reimbursed amount with interest during the entire contract term. As a result, the Company recognized a lease incentive asset in an amount of $1,030 that is deducted from the operating lease right-of-use asset. As a part of the agreement, BiomX Israel provided a bank guarantee to the landlord in the amount of approximately $270, representing four monthly lease and related payments.

On October 1, 2020, the Company entered into a lease agreement for office space in Branford, Connecticut, U.S., for 25 months beginning on October 5, 2020. Monthly lease payments under the agreement are approximately $4. As part of the agreement, the Company deposited $8 as a security, representing two monthly lease and related payments.

Lease expenses recorded in the consolidated statements of operations were $706 and $416 for the years ended December 31, 2021 and 2020, respectively.

(USD in thousands, except share and per share data)

**NOTE 8 - LEASES (Cont.)**

Supplemental cash flow information related to operating leases was as follows:

| | Year ended December 31, 2021 | Year ended December 31, 2020 |
|---|---|---|
| Cash payments for operating leases | 895 | 416 |

As of December 31, 2021, the Company's operating leases had a weighted average remaining lease term of 8.9 years and a weighted average discount rate of 6%. The maturity analysis of operating leases as of December 31, 2021 were as follows:

| | Operating Leases |
|---|---|
| 2022 | 832 |
| 2023 | 789 |
| 2024 | 789 |
| 2025 | 789 |
| 2026 | 789 |
| 2027 | 789 |
| 2028 | 789 |
| 2029 | 789 |
| 2030 | 722 |
| Total operating lease payments | 7,077 |
| Less imputed interest | (1,471) |
| Total operating lease liability balance | 5,606 |

**NOTE 9 - OTHER ACCOUNT PAYABLES**

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Employees and related institutions | 2,909 | 2,441 |
| Accrued expenses | 2,272 | 1,128 |
| Government institutions | 272 | 344 |
| Deferred income | - | 65 |
| | 5,453 | 3,978 |

**NOTE 10 - BALANCES AND TRANSACTION WITH RELATED PARTIES**

**A. Balances with related parties**

| | As of December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Additional paid in capital (treasury stock) (See 1 below) | (19) | (19) |

**NOTE 10 - BALANCES AND TRANSACTION WITH RELATED PARTIES (Cont.)**

**B. Transactions with related parties**

**1.** In October 2019, BiomX Israel entered into a loan agreement in the amount of $19 with a shareholder who was subject to taxation in Israel in connection with the Recapitalization Transaction. The loan was initially for a period of up to two years from the time of the grant, is non-recourse, and is secured by shares of Common Stock issued to them with a value that equals three times the loan amount at the time of the grant. If the shareholder defaults on such loan, the Company will have the right to forfeit or sell such number of shares with a value equal to the amount of the loan not timely repaid (plus interest accrued thereon), based on their market price at the time of such forfeiture or sale. The number of shares of Common Stock in respect of which the loan was granted was 5,700. The granting of the loan and the restrictions imposed on the related Common Stock until repayment of the loan were accounted as an acquisition of treasury stock by the Company at an amount equal to the loan.

**2.** On October 31, 2018, BiomX Israel entered into a research collaboration agreement with Janssen Research & Development, LLC ("Janssen"), an affiliate of shareholder Johnson & Johnson Development Corporation, for a collaboration on biomarker discovery for inflammatory bowel disease ("IBD"). Under the agreement, BiomX Israel is eligible to receive fees totaling $167 in installments of $50 within 60 days of signing of the agreement, $17 upon completion of data processing, and two installments of $50 each, upon delivery of Signature Phase I of the Final Study Report (both terms defined within the agreement). This agreement ended in 2020, 30 days after the parties completed the research program and BiomX Israel provided Janssen with a final study report. As of December 31, 2019, consideration of $117 had been received. The remaining $50 consideration was received in January 2020.

**3.** Refer to Note 13A regarding a Securities Purchase Agreement with institutional investors, all of the Company's directors and certain executive officers.

**4.** Refer to Note 13B regarding stock options granted to related parties.

**NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES**

**A.** During 2015, 2016 and 2017, BiomX Israel submitted three requests to the IIA for R&D projects for the technological incubators program. The approved budget per year was NIS 2,700 (approximately $781) per request. IIA funded 85% of the approved budget. As of December 31, 2021, BiomX Israel had received all funds with respect to these programs.

During 2019, the IIA approved two applications for a total budget of NIS 15,015 (approximately $4,308). IIA funded 30% of the approved budget. As of December 31, 2021, BiomX Israel had received all funds with respect to these programs.

**NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)**

In April 2020, the IIA approved an application for a total budget of NIS 15,562 (approximately $4,287). The IIA committed to fund 30% of the approved budget. The program was for the period beginning January 2020 through December 2020. As of December 31, 2021, BiomX Israel had received all funds with respect to this program.

In March 2021, the IIA approved two new applications for a total budget of NIS 19,444 (approximately $5,874). The IIA committed to fund 30% of the approved budget. The program is for the period beginning January 2021 through December 2021. As of December 31, 2021, BiomX Israel had received NIS 2,042 (approximately $625) from the IIA with respect to these programs.

In August 2021, the IIA approved an application for an aggregate budget of NIS 5,737 (approximately $1,778). The IIA committed to fund 50% of the approved budget. The program is for the period beginning July 2021 through June 2022. The program does not bear royalties. As of December 31, 2021, BiomX Israel had received NIS 1,004 (approximately $313) from the IIA with respect to this program. Refer to note 19A for more information regarding received funds.

Refer to note 19B for more information regarding approved applications in 2022.

According to the agreements with the IIA, BiomX Israel will pay royalties of 3% to 3.5% of future sales up to an amount equal to the accumulated grant received including annual interest of LIBOR linked to the dollar. BiomX Israel may be required to pay additional royalties upon the occurrence of certain events as determined by the IIA, that are within the control of BiomX Israel. No such events have occurred or were probable of occurrence as of the balance sheet date with respect to these royalties. Repayment of the grant is contingent upon the successful completion of the BiomX Israel's R&D programs and generating sales. BiomX Israel has no obligation to repay these grants if the R&D program fails, is unsuccessful or aborted or if no sales are generated. The Company had not yet generated sales as of December 31, 2021; therefore, no liability was recorded in these consolidated financial statements. IIA grants are recorded as a reduction of R&D expenses, net.

Total research and development income recorded in the consolidated statements of operations was $3,741 and $518 for the years ended December 31, 2021 and 2020, respectively.

Through December 31, 2021, total grants approved from the IIA aggregated to approximately $7,175 (NIS 24,782). Through December 31, 2021, BiomX Israel had received an aggregate amount of $5,571 (NIS 19,100) in the form of grants from the IIA. Total grants subject to royalties' payments aggregated to approximately $5,258. As of December 31, 2021, BiomX Israel had a contingent obligation to the IIA in the amount of approximately $5,397 including annual interest of LIBOR linked to the dollar.

Even though the IIA did not determine an alternative benchmark rate to the LIBOR, the Company does not expect the replacement to have a material impact on its financial statements.

**B.** In June 2015, BiomX Israel entered into a Research and License Agreement (the "2015 License Agreement") as amended with Yeda Research and Development Company Limited ("Yeda"), according to which Yeda undertakes to procure the performance of certain research, including proof-of-concept studies testing in-vivo phage eradication against a model bacteria in germ-free mice, development of an IBD model in animals under germ-free conditions and establishing an in-vivo method for measuring immune induction capability (Th1) of bacteria, followed by testing several candidate IBD inducing bacterial strains during the research period, as defined in the 2015 License Agreement and subject to the terms and conditions specified in the 2015 License Agreement. BiomX Israel contributed an aggregate of approximately $1,800 to the research budget agreed upon in the 2015 License Agreement. In addition, Yeda granted BiomX Israel an exclusive worldwide license for the development, production and sale of the products, as defined and subject to the terms and conditions specified in the 2015 License Agreement. In return, BiomX Israel is obligated to pay Yeda annual license fees of approximately $10 and royalties on revenues as defined in the 2015 License Agreement. In addition, in the event of certain mergers and acquisitions by the Company, Yeda will be entitled to an amount equivalent to 1% of the consideration received under such transaction (the "Exit Fee"), as adjusted per the terms of the 2015 License Agreement. As the Company has not yet generated revenue from operations, no provision was included in the consolidated financial statements as of December 31, 2021 and 2020 with respect to the 2015 License Agreement.

In May 2017, BiomX Israel signed an additional agreement with Yeda (the "2017 License Agreement"), according to which Yeda provided a license to the Company. As consideration for the license, BiomX granted Yeda 591,382 warrants to purchase shares of Common Stock. Refer to Note 13 below for the terms of the warrants granted.

In July 2019, the Company and Yeda amended the 2015 License Agreement and the 2017 License Agreement (the "Yeda Amendment"). Pursuant to the Yeda Amendment, following the closing of the Recapitalization Transaction, the provisions of the Yeda license agreements related to the Exit Fee were amended so that the Company is obligated to pay Yeda a one-time payment as described in the Yeda Amendment which will not exceed 1% of the consideration received in the event of any merger or acquisition involving the Company instead of the Exit Fee, with respect to each license agreement.

The 2017 License Agreement was terminated in 2020. Refer to Note 13 below for the terms of the warrants granted and the resulting impact due to the termination.

**NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)**

**C.** In April 2017, BiomX Israel signed an exclusive patent license agreement (the "2017 Patent License Agreement") with the Massachusetts Institute of Technology ("MIT") covering methods to synthetically engineer phage. According to the agreement, BiomX Israel received an exclusive, royalty-bearing license to certain patents held by MIT. In return, BiomX Israel paid an initial license fee of $25 during the year 2017 and is required to pay certain license maintenance fees of up to $250 in each subsequent year and following the commercial sale of licensed products. BiomX Israel is also required to make payments to MIT upon the satisfaction of development and commercialization milestones totaling up to $2,350 in aggregate, as well as royalty payments on future revenues. No liability is included in the consolidated financial statements as of December 31, 2021 with respect to this agreement. The consolidated financial statements as of December 31, 2020 include a liability with respect to this agreement in the amount of $240 recorded as other liabilities.

In October 2020, the Company and MIT amended the 2017 Patent License Agreement. Pursuant to the MIT Amendment, BiomX Israel will continue to receive an exclusive, royalty-bearing license to certain patents held by MIT. In return, BiomX Israel is required to pay certain license maintenance fees of up to $250 in each subsequent year and following the commercial sale of licensed products. BiomX Israel is also required to make payments to MIT upon the satisfaction of development and commercialization milestones totaling up to $4,700 in aggregate, as well as royalty payments on future revenues.

**D.** As successor in interest to RondinX Ltd., BiomX Israel is a party to a license agreement dated March 20, 2016 with Yeda, pursuant to which the Company has a worldwide exclusive license to Yeda's know-how, information and patents related to the Company's meta-genomics target discovery platform. As consideration for the license, the Company is obligated to pay annual license fees of $10, subject to the terms and conditions of the agreement. Either party has the option to terminate the agreement at any time by way of notice to the other party, as outlined in the agreement. In addition, the Company is obligated to pay a royalty in the low single digits based on revenue of products. The consolidated financial statements as of December 31, 2021 and 2020 include a liability with respect to this agreement in the amount of $175 and $83, respectively, recorded as other liabilities. Refer to Note 6 regarding a contingent consideration with respect to the RondinX Ltd. acquisition.

**E.** In December 2017, BiomX Israel signed a patent license agreement with Keio University and JSR Corporation in Japan. According to the agreement, BiomX Israel received an exclusive patent license to certain patent rights related to the Company's IBD program. In return, the Company will pay an annual license fee of between $15 and $25 subject to the terms and conditions specified in the agreement. Additionally, the Company is obligated to make additional payments based upon the achievement of clinical and regulatory milestones up to an aggregate of $32,100 and royalty payments based on future revenue. As the Company has not yet generated revenue from operations and the achievement of certain milestones is not probable, no provision was included in the consolidated financial statements as of December 31, 2021 and 2020 with respect to the agreement.

**NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)**

In April 2019, BiomX Israel signed an additional patent license agreement with Keio University and JSR Corporation in Japan. According to the agreement, BiomX Israel received an exclusive sublicense by JSR to certain patent rights related to the Company's Primary Sclerosing Cholangitis program. In return, the Company is required (i) to pay a license issue fee of $20 and annual license fees ranging from $15 to $25 (ii) make additional payments based upon the achievement of clinical and regulatory milestones up to an aggregate of $32,100 and (iii) make tiered royalty payments, in the low single digits based on future revenue. The consolidated financial statements include liabilities with respect to this agreement in the amount of $40 and $378 as of December 31, 2021 and 2020, respectively, recorded as other liabilities.

**F.** On September 1, 2020 ("Effective Date"), BiomX Israel entered into a research collaboration agreement with Boehringer Ingelheim International GmbH ("BI") for a collaboration on biomarker discovery for IBD. Under the agreement, BiomX Israel was eligible to receive fees totaling $439 in installments of $50 within 60 days of the Effective Date, $100 upon receipt of the BI materials, $150 upon the completion of data processing and $139 upon delivery of the Final Report of observations and Results of the Project (as such terms are defined within the agreement). The Company granted BI an option to negotiate for an exclusive, worldwide, compensation-based license(s), with rights to sublicense, to use the metagenomic signature results under any patents covering such metagenomic signature results for the sole purpose of making, having made, offering for sale, selling, having sold, importing or otherwise commercializing diagnostic products, including companion diagnostics (the "Option"). The Option shall be exercisable any time until twelve months following delivery of the Final Report. BI agreed to pay to the Company fifty percent (50%) of all income that BI receives as a result of, and directly related to, the commercial exploitation of such companion diagnostic. During 2021, consideration of $150 was received. As of December 31, 2021, the total consideration of $439 had been received. The consideration is recorded as a reduction of R&D expenses, net in the consolidated statements of operations.

**G.** Refer to Note 8 for information regarding the Company's lease liabilities.

**NOTE 12 - LONG-TERM DEBT**

On August 16, 2021, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules"), with respect to a venture debt facility. Under the Loan Agreement, Hercules provided the Company with access to a term loan with an aggregate principal amount of up to $30,000 (the "Term Loan Facility"), available in three tranches, subject to certain terms and conditions. The first tranche of $15,000 was advanced to the Company on the date the Loan Agreement was executed. Upon the occurrence of specified milestones and continuing through December 31, 2022, a loan in the aggregate principal amount of up to $10,000 ("the second tranche"), and upon the occurrence of specified milestones and continuing through September 30, 2023, a loan in the aggregate principal amount of up to $5,000 ("the third tranche"), may become available. The milestones for the remaining tranches have not yet been reached as of December 31, 2021. The Company is required to make interest only payments through March 1, 2023, or extended to September 1, 2023 upon satisfaction of certain milestones, and is required to then repay the principal balance and interest in equal monthly installments through September 1, 2025.

The Company may prepay advances under the Loan Agreement, in whole or in part, at any time subject to a prepayment charge equal to: (a) 3.0 % of amounts prepaid, if such prepayment occurs during the first 12 months following the closing date; (b) 2.0% after 12 months but prior to 24 months; (c) 1.0% after 24 months but prior to 36 months, and (d) no charge after 36 months. Upon prepayment or repayment of all or any of the term loans under the Term Loan Facility, the Company is required to pay an end of term charge ("End of Term Charge") equal to 6.55% of the total aggregate amount of the term loans being prepaid or repaid.

Interest on the term loan accrues at a per annum rate equal to the greater of (i) the Prime Rate as reported in The Wall Street Journal plus 5.70% and (ii) 8.95%. On December 31, 2021, the Prime Rate was 3.25%. Interest expense is calculated using the effective interest method and is inclusive of non-cash amortization of capitalized loan issuance costs. Debt issuance costs are recorded on the consolidated balance sheet as a reduction of liabilities. Amounts allocated to the debt, net of issuance cost, are subsequently recognized at amortized cost using the effective interest method. On December 31, 2021, the effective interest rate was 13.73%.

(USD in thousands, except share and per share data)

**NOTE 12 - LONG-TERM DEBT(cont.)**

As of December 31, 2021, the carrying value of the term loan consists of $15,000 principal outstanding less the debt discount and issuance costs of approximately $775. The End of Term Charge of $983 is recognized over the life of the term loan as interest expense using the effective interest method. The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan.

Interest expense relating to the term loan, which is included in interest expense in the consolidated statements of operations was $699 for the year ended December 31, 2021.

Under the terms of the Loan Agreement, the Company granted first priority liens and security interests in substantially all of the Company's intellectual property as collateral for the obligations thereunder. The Company also granted Hercules the right, at their discretion, to participate in any closing of any single subsequent broadly marketed financing as defined up to a maximum aggregate amount of $2,000 under the terms as afforded to other investors in such financing. The Loan Agreement also contains representations and warranties by the Company and Hercules, indemnification provisions in favor of Hercules and customary affirmative and negative covenants, including a liquidity covenant beginning October 1, 2022, requiring the Company to maintain a minimum aggregate compensating cash balance of $5,000, and events of default, including a material adverse change in the Company's business, payment defaults, breaches of covenants following any applicable cure period, and a material impairment in the perfection or priority of Hercules' security interest in the collateral. In the event of default by the Company under the Loan Agreement, the Company may be required to repay all amounts then outstanding under the Loan Agreement.

Future principal payments for the long-term debt are as follows:

| | December 31, 2021 |
|---|---|
| 2022 | - |
| 2023 | 4,458 |
| 2024 | 5,804 |
| 2025 | 4,738 |
| Total principal payments | 15,000 |
| Unamortized discount and debt issuance costs | (590) |
| Long-term debt | 14,410 |

**NOTE 13 - STOCKHOLDERS EQUITY**

**A. Share Capital:**

**Common Stock:**

The Company is authorized to issue 60,000,000 shares of Common Stock. Holders of the Company's Common Stock are entitled to one vote for each share.

**Treasury Stock:**

Refer to Note 10B(1).

**Initial Public Offering:**

On December 18, 2018, the Company consummated its initial public offering ("IPO") of 7,000,000 units ("Public Units"). The Public Units sold in the IPO were sold at an offering price of $10.00 per Public Unit, generating total gross proceeds of $70,000. The Public Units each consist of one share of Common Stock and one warrant to purchase one-half of a share of Common Stock ("Public Warrant"), with every two Public Warrants entitling the holder to purchase one share of Common Stock for $11.50 per full share.

Following the Recapitalization Transaction, the Company retained approximately $60,100 balance held in a trust account, after redemptions of IPO shares held by certain shareholders.

Simultaneous with the consummation of the IPO, the Company consummated the private placement of an aggregate of 2,900,000 warrants ("Private Placement Warrants").

**NOTE 13 - STOCKHOLDERS EQUITY (Cont.)**

**A. Share Capital: (Cont.)**

**Stock Exchange:**

As detailed in Note 1, as part of the Recapitalization Transaction on October 28, 2019, the Company issued 15,069,058 shares of Common Stock in exchange for approximately 65% of the issued and outstanding ordinary shares and all the preferred shares of BiomX Israel. The number of shares prior to the Recapitalization Transaction has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the Recapitalization Transaction.

In addition, the Company also agreed to issue the following number of additional shares of Common Stock, in the aggregate, to stockholders on a pro rata basis, subject to the Company's achievement of the conditions specified below following the recapitalization transaction (all with respect to the Company's Common Stock traded on the NYSE American):

A. 2,000,000 additional shares of the Company's Common Stock if the daily volume weighted average price of the Company's Common Stock in any 20 trading days within a 30-trading day period prior to January 1, 2022 is greater than or equal to $16.50 per share. As of December 31, 2021, the condition was not achieved and the Company's conditional undertaking to issue additional shares expired.

B. 2,000,000 additional shares of the Company's Common Stock if the daily volume weighted average price of the Company's Common Stock in any 20 trading days within a 30-trading day period prior to January 1, 2024 is greater than or equal to $22.75 per share.

C. 2,000,000 additional shares of the Company's Common Stock if the daily volume weighted average price of the Company's Common Stock in any 20 trading days within a 30-trading day period prior to January 1, 2026 is greater than or equal to $29.00 per share.

**At-the-market Sales Agreement:**

In December 2020, pursuant to a registration statement on Form S-3 declared effective by the Securities and Exchange Commission on December 11, 2020, the Company entered into an Open Market Issuance Sales Agreement ("ATM Agreement") with Jefferies LLC. ("Jefferies"), which provides that, upon the terms and subject to the conditions and limitations in the ATM Agreement, the Company may elect, from time to time, to offer and sell shares of Common Stock having an aggregate offering price of up to $50,000 through Jefferies acting as sales agent. During the year ended December 31, 2021, the Company sold 743,964 shares of Common Stock under the ATM Agreement, at an average price of $7.19 per share, raising aggregate net proceeds of approximately $5,188, after deducting an aggregate commission of 3%. During the year ended December 31, 2020, the Company sold 10,176 shares of Common Stock under the ATM Agreement, at an average price of $6.07 per share, raising aggregate net proceeds of approximately $60, after deducting an aggregate commission of 3%. The Company deducted issuance expenses from Additional Paid in Capital of $2 and $158 as of December 31, 2021 and 2020, respectively.

**Securities Purchase Agreement:**

On July 26, 2021, the Company entered into a Securities Purchase Agreement with institutional investors, all of the Company's directors and certain executive officers for the sale of an aggregate of 3,750,000 shares of the Company's Common Stock and warrants to purchase an aggregate of 2,812,501 shares of the Company's Common Stock in a registered direct offering (the "Registered Direct Offering"), for gross proceeds of $15,000 before deducting placement agent fees and offering expenses and assuming that none of the warrants are exercised. The securities were sold at price of $4.00 per share and an accompanying warrant to purchase 0.75 of a share of the Company's Common Stock at an exercise price of $5.00 per share. The warrants will be exercisable six months after the date of issuance and will expire five years from the date such warrant first becomes exercisable. The warrants issued were classified as equity in accordance with ASC 815-40. The securities were offered pursuant to the Company's effective registration statement on Form S-3. All proceeds were received as of July 28, 2021. 125,000 shares of Common Stock and 93,750 warrants were sold to related parties.

**Maruho Agreement:**

In October 2021, the Company entered into a Stock Purchase Agreement with a subsidiary of Maruho Co. Ltd., ("Maruho"), a leading dermatology-focused pharmaceutical company in Japan, pursuant to which the Company issued to Maruho 375,000 shares of Common Stock at a price of $8.00 per share for gross proceeds of $3,000. The company also granted Maruho a right of first offer to license its atopic dermatitis product candidate, BX005, in Japan. The right of first offer will commence following the availability of results from the Phase 1/2 study expected in 2022. The Company applied ASC 606 by analogy to the agreements. The agreements were combined into a single unit of account for the purpose of applying ASC 606. Part of the consideration paid under the agreements, equal to the grant date fair value of the shares issued to Maruho of $1,024, is attributed to the issuance of shares and accounted for as an increase in equity. The remainder of $1,976 was attributed to a contract liability, to be recognized as other income, at a point in time, once the clinical trials related to the product candidate are completed.

**NOTE 13 - STOCKHOLDERS EQUITY (Cont.)**

**A. Share Capital: (cont.)**

**CFF Agreement:**

In December 2021, the Company entered into a Securities Purchase Agreement with the Cystic Fibrosis Foundation ("CF Foundation"), an organization that historically played a role in supporting the development of innovative therapies for patients suffering from cystic fibrosis (CF). Under the terms of the agreement, the Company will receive up to $5,000 in two tranches. In the first tranche, which closed and fully received on December 21, 2021, the CF Foundation invested $3,000 as an initial equity investment based on a share price of $2.57. Upon completion of patient dosing in Part 1 of the Company's Phase 1b/2a study of BX004, the Company would have the right to receive the second tranche of $2,000, also as an equity investment. In the event that the average closing price of the Common Stock for the ten trading days prior to the second tranche completion is less than $2.57, the Company shall have the right in its sole discretion to waive the second tranche payment and in such event the CF Foundation shall not have any right to receive additional shares. However, the CF foundation may waive the Milestone in its discretion and make the Milestone Payment nonetheless. The Company concluded that the second tranche is a freestanding financial instrument. The Company also concluded that since the instrument will be predominantly settled in a variable number of shares at a fixed monetary amount, the second tranche is in the scope of ASC 480 and should be accounted for at fair value with subsequent changes in fair value recognized in the statements of operations in each period. The Company further determined that due to the settlement mechanism, the fair value of the second tranche is negligible, both at inception and on December 31, 2021.

**Preferred Stock:**

The Company is authorized to issue 1,000,000 shares of preferred stock with a par value of $0.0001 per share with such designation, rights and preferences as may be determined from time to time by the Company's Board of Directors (the "Board").

**Warrants:**

1. The Private Placement Warrants are identical to the Public Warrants underlying the Units sold in the IPO except that the Private Placement Warrants are exercisable for cash (even if a registration statement covering the shares of Common Stock issuable upon exercise of such warrants is not effective) or on a cashless basis, at the holder's option, and will not be redeemable by the Company, in each case, so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

2. The Public Warrants became exercisable upon the closing of the Recapitalization Transaction. No fractional shares will be issued upon exercise of the Public Warrants. Therefore, the Public Warrants must be exercised in multiples of two warrants. The Public Warrants will expire five years after the completion of the Recapitalization Transaction or earlier upon redemption or liquidation.

   The Company may redeem the Public Warrants:

   - in whole and not in part;
   - at a price of $0.01 per warrant;
   - at any time during the exercise period;
   - upon a minimum of 30 days prior written notice of redemption;
   - if, and only if, the last sale price of the Company's Common Stock equals or exceeds $16.00 per share for any 20 trading days within a 30-trading day period ending on the third business day prior to the date on which the Company sends the notice of redemption to the warrant holders; and
   - if, and only if, there is a current registration statement in effect with respect to the shares of Common Stock underlying such warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption.

   If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement. The exercise price and number of shares of Common Stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. However, the warrants will not be adjusted for issuance of Common Stock at a price below their exercise price. Additionally, in no event will the Company be required to net cash settle the warrants.

(USD in thousands, except share and per share data)

**NOTE 13 - STOCKHOLDERS EQUITY (Cont.)**

**A. Share Capital: (cont.)**

As of December 31, 2021, the Company had the following outstanding warrants to purchase Common Stock issued to stockholders:

| Warrant | Issuance Date | Expiration Date | Exercise Price Per Share | Number of Shares of Common Stock Underlying Warrants |
|---|---|---|---|---|
| Private Placement Warrants | IPO (December 13, 2018) | December 13, 2023 | 11.50 | 2,900,000 |
| Public Warrants | IPO (December 13, 2018) | October 28, 2024 | 11.50 | 3,500,000 |
| 2021 Registered Direct Offering Warrants | SPA (July 28, 2021) | January 28, 2027 | 5.00 | 2,812,501 |
| | | | | 9,212,501 |

**B. Stock-based compensation:**

**Equity Incentive Plan:**

In 2015, the Board of Directors of BiomX Israel approved a plan for the allocation of options to employees, service providers, and officers (the "2015 Plan"). The options represented a right to purchase one Ordinary Share of the BiomX Israel in consideration of the payment of an exercise price. Also, the options were granted in accordance with the "capital gains route" under section 102 and section 3(i) of the Israeli Income Tax Ordinance and section 409A of the U.S. Internal Revenue Code.

The 2015 plan was adjusted following the Recapitalization Transaction on October 28, 2019 such that each outstanding option entitles its holder to purchase one share of Common Stock of the Company. As a result, the number of options and exercise price per share were adjusted in a technical manner such that there was no change in the fair value of the awards under the adjusted 2015 Plan. The number of outstanding options and exercise prices in this Note have been restated to reflect the adjusted 2015 Plan.

As of December 31, 2021, there are no shares of Common Stock remaining for issuance under the 2015 Plan.

In 2019, the Company adopted a new incentive plan (the "2019 Plan") to grant 1,000 options, exercisable for Common Stock.

The aggregate number of shares of Common Stock that may be delivered pursuant to the 2019 Plan will automatically increase on January 1 of each year, commencing on January 1, 2020 and ending on (and including) January 1, 2029, in an amount equal to four percent (4%) of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year.

Notwithstanding the foregoing, the Board may act prior to January 1 of a given year to provide that there will be no January 1 increase for such year or that the increase for such year will be a lesser number of shares of Common Stock than provided herein.

As of December 31, 2021, there were 216,036 shares of Common Stock remaining for issuance under the 2019 plan. On January 1, 2022, the number of shares of Common Stock available to grant under the 2019 Plan was increased by 1,190,129.

(USD in thousands, except share and per share data)

**NOTE 13 - STOCKHOLDERS EQUITY (Cont.)**

**B. Stock-based compensation: (Cont.)**

**Stock Options:**

On March 25, 2020, the Board approved the grant of 814,700 options without consideration to 65 employees, one consultant, four senior officers (one of whom is also a consultant), and six directors under the 2019 Plan. These options were granted at an exercise price of $6.21 per share with vesting periods ranging from three to four years. Directors and senior officers are entitled to full acceleration of their unvested options upon the occurrence of both a change in control of the Company and the end of their engagement with the Company.

On May 5, 2020, the Board approved the grant of 79,000 options without consideration to four employees under the 2019 Plan. These options were granted at an exercise price of $5.59 per share with a vesting period of four years.

On October 2, 2020, the Board approved the grant of 32,000 options without consideration to two directors under the 2019 Plan. These options were granted at an exercise price of $6.44 per share with a vesting period of four years. Directors are entitled to full acceleration of their unvested options upon the occurrence of both a change in control of the Company and the end of their engagement with the Company.

On March 30, 2021, the Board approved the grant of 985,530 options to 94 employees, including five senior officers, one consultant, and six directors under the 2019 Plan, without consideration. Options were granted at an exercise price of $7.02 per share with a vesting period of four years. Directors and senior officers are entitled to full acceleration of their unvested options upon the occurrence of both a change in control of the Company and the end of their engagement with the Company.

The fair value of each option was estimated as of the date of grant or reporting period using the Black-Scholes option-pricing model using the following assumptions:

| | 2021 | 2020 |
|---|---|---|
| Underlying value of Common Stock ($) | 7.02 | 5.59-6.44 |
| Exercise price ($) | 7.02 | 5.59-6.44 |
| Expected volatility (%) | 85.0 | 85.0 |
| Expected terms of the option (years) | 6.11 | 6.11 |
| Risk-free interest rate (%) | 1.17 | 0.39-0.68 |

The cost of the benefit embodied in the options granted in 2021 and 2020 based on their fair value as at the grant date, is estimated to be $5,138 and $3,752, respectively. These amounts will be recognized in statements of operations over the vesting period.

As of December 31, 2021, the unrecognized compensation cost related to all unvested, equity classified stock options of $3,395 is expected to be recognized as an expense on a graded vesting method over a weighted-average period of 1.43 years.

(USD in thousands, except share and per share data)

**NOTE 13 - STOCKHOLDERS EQUITY (Cont.)**

**B. Stock-based compensation: (Cont.)**

**Stock Options: (Cont.)**

A summary of options granted to purchase the Company's Common Stock under the Company's stock option plans are as follows:

| | For year ended December 31, 2021 | | |
|---|---|---|---|
| | Number of Options | Weighted average exercise price | Aggregate intrinsic value |
| Outstanding at the beginning of period | 3,569,766 | $ 3.12 | $ 12,338 |
| Granted | 985,530 | 7.02 | |
| Forfeited | (386,508) | 4.60 | |
| Exercised | (84,239) | $ 1.55 | |
| Outstanding at the end of period | 4,084,549 | 3.95 | $ 671 |
| Vested at end of period | 2,486,381 | | |
| Weighted average remaining contractual life – years as of December 31, 2021 | 6.82 | | |

| | For year ended December 31, 2020 | | |
|---|---|---|---|
| | Number of Options | Weighted average exercise price | Aggregate intrinsic value |
| Outstanding at the beginning of period | 3,143,802 | $ 1.61 | $ 25,733 |
| Granted | 925,700 | 6.17 | |
| Forfeited | (108,110) | 4.66 | |
| Exercised | (391,626) | $ 0.79 | |
| Outstanding at the end of period | 3,569,766 | $ 3.12 | $ 12,338 |
| Vested at end of period | 2,334,037 | | |
| Weighted average remaining contractual life – years as of December 31, 2020 | 7.62 | | |

(USD in thousands, except share and per share data)

**NOTE 13 - STOCKHOLDERS EQUITY (Cont.)**

**B. Stock-based compensation: (Cont.)**

**Warrants:**

As of December 31, 2021, and 2020, the Company had the following outstanding compensation related warrants to purchase Common Stock as follows:

| Warrant | Issuance Date | Expiration Date | Exercise Price Per Share | Number of Shares of Common Stock Underlying Warrants |
|---|---|---|---|---|
| Private Warrants issued to Yeda (see 1 below) | May 11, 2017 | May 11, 2025 | (*) | - |
| Private Warrants issued to scientific founders (see 2 below) | November 27, 2017 | | - | 2,974 |
| | | | | 2,974 |

(*) less than $0.001.

**1.** In May 2017, in accordance with the 2017 License Agreement (see also Note 11B), the Company issued to Yeda, 591,382 warrants to purchase Common Stock at $0.0001 nominal value, for nominal consideration. Yeda has the option to exercise the warrants on a cashless basis. In 2020, the 2017 License Agreement was terminated.

On March 10, 2021, Yeda exercised 362,444 warrants on a cashless basis, resulting in the issuance of 362,383 shares of Common Stock. The remainder of the warrants were forfeited as part of the termination of the license agreement.

For the year ended December 31, 2021, the Company did not record an expense or income related to warrants. For the year ended December 31, 2020, the Company recorded expense of $233. Expenses and income are included in R&D expenses, net in the consolidated statements of operations.

236,552 warrants were fully vested and exercisable on the date of their issuance. The remainder of the warrants will vest and become exercisable subject to achievement of certain milestones specified in the agreement as follows:

a. 177,414 upon the filing of a patent application covering any Discovered Target or a Product (both as defined in the 2017 License Agreement). In 2020 the warrants were forfeited following termination of the 2017 License Agreement,

(USD in thousands, except share and per share data)

**NOTE 13 - STOCKHOLDERS EQUITY (Cont.)**

**B. Stock-based compensation: (Cont.)**

**Warrants: (Cont.)**

b. 118,277 upon achievement of the earlier of the following milestone by the Company:

(i) execution of an agreement with a pharmaceutical company with respect to the commercialization of any of the Company's licensed technology or the Consulting IP or a Product (both defined in the 2017 License Agreement) or

(ii) the filing of a patent application covering any Discovered Target (as defined in the 2017 License Agreement) or a Product.

In the case of termination of the 2017 License Agreement after the second anniversary thereof, and provided that none of the aforementioned milestones has been attained prior to such termination, the warrants will vest upon such termination.

As of December 31, 2020, 118,277 warrants were vested as the 2017 License Agreement was terminated after the second anniversary with no milestone have been attained.

c. 59,139 upon completion of a Phase 1 clinical trial in respect of a Product (as defined in the 2017 License Agreement). In 2020 the warrants were forfeited following the termination of the 2017 License Agreement.

**2.** In November 2017, BiomX Israel issued 7,615 warrants to Yeda and 2,974 warrants to its founders. All the warrants were fully vested at their grant date and will expire immediately prior to a consummation of an M&A transaction. The warrants did not expire as a result of the Recapitalization Transaction and have no exercise price. No compensation expenses were recorded in the financial statements during 2021 and 2020.

The following table sets forth the total stock-based payment expenses resulting from options and warrants granted, included in the statements of operations:

| | Year ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Research and development expenses, net | 1,770 | 1,815 |
| General and administrative | 1,467 | 1,075 |
| | 3,237 | 2,890 |

The Company recognized stock-based compensation expenses in connection with options granted to executive officers of the Company in the amount of $1,102 and $1,384 for the years ended December 31, 2021 and 2020, respectively.

(USD in thousands, except share and per share data)

## NOTE 14 - RESEARCH AND DEVELOPMENT EXPENSES, NET

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Professional service and subcontractors | 9,458 | 6,576 |
| Salaries and related expenses | 12,287 | 9,210 |
| Stock-based compensation | 1,770 | 1,815 |
| Depreciation | 986 | 652 |
| Materials and supplies | 1,738 | 1,094 |
| Rent and related expenses | 1,008 | 664 |
| Other | 55 | 84 |
| | 27,302 | 20,095 |
| Less change in contingent liabilities (see Note 11C, 11E) | (578) | - |
| Less income from collaboration agreements (see Note 11H, 10B2) | (307) | (160) |
| Less grants from the IIA (see Note 11A) | (3,741) | (518) |
| | 22,676 | 19,417 |

## NOTE 15 - GENERAL AND ADMINISTRATIVE EXPENSES

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Salaries and related expenses | 2,895 | 2,757 |
| Stock-based compensation | 1,467 | 1,075 |
| Professional services | 2,029 | 1,648 |
| Travel expenses | 140 | 173 |
| Recruitment expenses | 375 | 170 |
| Rent and related expenses | 291 | 262 |
| Insurance expenses | 2,495 | 1,985 |
| Other | 1,575 | 1,253 |
| | 11,267 | 9,323 |

## NOTE 16 - FINANCE INCOME (EXPENSES), NET

| | Year ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Exchange rate differences | 237 | 511 |
| Interest income from bank deposits | (86) | (641) |
| Revaluation of contingent liabilities | - | 116 |
| Bank fees and other | 7 | 7 |
| Income from foreign exchange contracts | (160) | (165) |
| | (2) | (172) |

(USD in thousands, except share and per share data)

## NOTE 17 - INCOME TAXES

**A.** The Company files income tax returns in the U.S. federal jurisdiction and in state and local jurisdictions and is subject to examination by the various taxing authorities. The Company's income tax returns since inception remain open and subject to examination. The statutory U.S. federal income tax rate is 21%. As of December 31, 2021, the Company had total net operating losses in the U.S. of approximately $7,478, which may be carried forward and offset against taxable income in the future.

**B.** BiomX Ltd. And RondinX Ltd. file income tax returns in Israel. Their tax assessments through 2016 are deemed to be final. The statutory Israeli income tax rate is 23%.

**C.** As of December 31, 2021 and 2020, BiomX Israel had total net operating losses in Israel of approximately $78,542 and $47,336, respectively, which may be carried forward and offset against taxable income in the future for an indefinite period.

**D.** As of December 31, 2021, the significant components of the Company's deferred tax assets are net operating loss carryforward in the amount of $20.2 million and research and development expenses in the amount of $4.6 million. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2021. Management reevaluates the positive and negative evidence at each reporting period.

**E.** The Company's policy is to record estimated interest and penalties related to uncertain tax positions in income tax expense. The Company has no amounts recorded for any unrecognized tax positions, accrued interest or penalties as of December 31, 2021 and 2020.

A reconciliation of the U.S. federal statutory tax rate and the effective tax rate is as follow:

| | As of December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Statutory U.S. federal income tax rate | (21)% | (21)% |
| U.S. vs foreign tax rate differential | (2) | (2) |
| Change in deferred tax asset valuation allowance | 23 | 23 |
| Effective tax rate | -% | -% |

Loss from operations, before taxes on income, consists of the following:

| | As of December 31, | |
|---|---|---|
| | **2021** | **2020** |
| United States | 4,571 | 3,273 |
| Israel | 31,655 | 26,813 |
| | 36,226 | 30,086 |

(USD and NIS in thousands, except share and per share data)

## NOTE 18 - BASIC LOSS PER SHARE

The basic and diluted net loss per share and weighted average number of shares of Common Stock used in the calculation of basic and diluted net loss per share are as follows:

| | For the year ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Net loss | 36,226 | 30,086 |
| Net loss per share | 1.39 | 1.30 |
| Weighted average number of Common Stock | 26,007,947 | 23,062,216 |

As the inclusion of shares of Common Stock equivalents in the calculation would be anti-dilutive for all periods presented, diluted net loss per share is the same as basic net loss per share.

Basic loss per share is computed on the basis of the net loss for the period divided by the weighted average number of shares of Common Stock outstanding during the period. Diluted loss per share is based upon the weighted average number of shares of Common Stock and of potential shares of Common Stock outstanding when dilutive. Potential shares of Common Stock equivalents include outstanding stock options and warrants, which are included under the treasury stock method when dilutive. The calculation of diluted loss per share as of December 31, 2021 does not include 4,084,545, 9,215,475 and 4,000,000 of shares underlying options, shares underlying warrants and contingent shares, respectively, because the effect would be anti-dilutive.

## NOTE 19 - SUBSEQUENT EVENTS

A. In January 2022, the Company received NIS 2,243 (approximately $721) from the IIA as part of the two approved programs in 2021, after submitting interim reports for the first six months of 2021.

B. In March 2022, the IIA approved a new application for a total budget of NIS 13,004 (approximately $4,022). The IIA committed to fund 30% of the approved budget. The program is for the period beginning January 2022 through December 2022.

C. In March 2022, the Board approved the grant of 1,153,500 options to 89 employees, one consultant, three senior officers and five directors under the 2019 Plan, without consideration. Options were granted at an exercise price of $1.41 per share with a vesting period of four years. Directors and senior officers are entitled to full acceleration of their unvested options upon the occurrence of both a change in control of the Company and the end of their engagement with the Company.

D. From January 1, 2022 through March 25, 2022, the Company issued an aggregate of 26,011 shares of Common Stock pursuant to the ATM Agreement for aggregate net proceeds of $35.

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM 10-K/A**
**Amendment No. 1**

**(Mark One)**
**☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2021**

**OR**

**☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from to**

**Commission File No. 001-38762**

# BIOMX INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **82-3364020** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **22 Einstein St., Floor 5, Ness Ziona, Israel** | **7414003** |
| (Address of principal executive offices) | (Zip Code) |

**+972 723942377**
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Units, each consisting of one share of common stock, $0.0001 par value, and one Warrant entitling the holder to receive one half share of common stock | PHGE.U | NYSE American |
| Common stock, $0.0001 par value | PHGE | NYSE American |
| Warrants, each exercisable for one-half of a share of common stock, $0.0001 par value, at an exercise price of $11.50 per share | PHGE.WS | NYSE American |

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

☐ Large accelerated filer
☒ Non-accelerated filer
☐ Accelerated filer
☒ Smaller reporting company
☒ Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

On June 30, 2021, the last day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the Registrant's shares of Common Stock held by non-affiliates of the Registrant was $119,922,575 based on the closing sale price of the Registrant's shares of Common Stock on June 30, 2021 (the last trading day of the fiscal quarter) of $5.46 per share.

The number of shares outstanding of the Registrant's shares of Common Stock as of April 28, 2022 was 29,780,409.

DOCUMENTS INCORPORATED BY REFERENCE

None

**Auditor Name: Brightman Almagor Zohar & Co.** **Auditor Location: Tel Aviv, Israel** **Auditor Firm ID: 1197**

## EXPLANATORY NOTE

BiomX Inc., or the Company, we, our or us) is filing this Amendment No. 1, or the Amended Report, to the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission, or the SEC, on March 30, 2022, or the Original Report, in order to add certain information required by Items 10-14 of Part III of Form 10-K, as well as certain additional exhibits. The Amended Report does not affect any other items in the Original Report.

Except as otherwise expressly stated for the Items amended in this Amended Report, this Amended Report continues to speak as of the date of the Original Report and we have not updated the disclosure contained herein to reflect events that have occurred since the filing of the Original Report. Accordingly, this Amended Report should be read in conjunction with the Original Report and our other filings made with the SEC subsequent to the filing of the Original Report.

Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, this Amendment also contains new certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Because no financial statements are included in this Amended Report and it does not contain or amend any disclosure with respect to Items 307 or 308 of Regulation S-K promulgated by the SEC under the Exchange Act, paragraphs 3, 4 and 5 of the Section 302 certifications have been omitted. In addition, because no financial statements are included in this Amended Report, new certifications of the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 are not required to be included with this Amended Report.

**BIOMX INC.**
**FORM 10-K/A**
**(Amendment No. 1)**
**FOR THE YEAR ENDED DECEMBER 31, 2021**

**TABLE OF CONTENTS**

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

Set forth below are the names, ages and positions of each of the individuals who serve as our executive officers and member of the Board of Directors, or Board, as of April 28, 2022.

| Name | Age | Position |
|---|---|---|
| ***Executive Officers*** | | |
| Jonathan Solomon | 45 | Chief Executive Officer and Director |
| Marina Wolfson | 38 | Chief Financial Officer |
| Assaf Oron | 47 | Chief Business Officer |
| Dr. Merav Bassan | 56 | Chief Development Officer |
| | | |
| ***Non-Employee Directors*** | | |
| Dr. Russell Greig(1)(2)(3) | 69 | Director and Chairman of the Board of Directors |
| Dr. Gbola Amusa(1) | 48 | Director |
| Jonas Grossman(2)(3) | 48 | Director |
| Dr. Alan Moses(2) | 74 | Director |
| Lynne Sullivan(1)(3) | 56 | Director |

(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating and corporate governance committee

**Executive Officers**

***Jonathan Solomon*** has served as the Chief Executive Officer and as a director of the Company since October 2019. Mr. Solomon served as Board member of BiomX Ltd., or BiomX Israel, from February 2016 and also as Chief Executive Officer from February 2017 to October 2019. From July 2007 to December 2015, Mr. Solomon was a co-founder, President, and Chief Executive Officer of ProClara Biosciences Inc. (formerly NeuroPhage Pharmaceuticals Inc.), a biotechnology company pioneering an approach to treating neurodegenerative diseases. Prior to joining ProClara, he served for ten years in a classified military unit of the Israeli Defense Forces. Mr. Solomon holds B.Sc. magna cum laude in Physics and Mathematics from the Hebrew University, an M.Sc. summa cum laude in Electrical Engineering from Tel Aviv University, and an MBA with honors from the Harvard Business School.

We believe that Mr. Solomon's qualifications to sit on our Board include his extensive board and management experience in the biotech industry.

***Marina Wolfson*** has served as the Chief Financial Officer of the Company since April 2022. Ms. Wolfson served as Senior Vice President of Finance and Operations of the Company from October 2020 to March 2022 and Vice President of Finance and Operations of the Company from December 2019 to October 2020. Ms. Wolfson's experience includes working with large pharmaceutical and hi-tech companies, as well as venture capital funds. Prior to joining the Company, Ms. Wolfson worked as Vice President of Finance at BioView Ltd. (TASE: BIOV) from 2010 to 2019 and a senior auditor at Ernst & Young, from 2007 to 2010. Ms. Wolfson is a certified public accountant in Israel and holds a B.A in Economics and Accounting (with honors) and an MBA (with honors, specializing in finance) from Ben-Gurion University.

***Assaf Oron*** has served as the Chief Business Officer of the Company since October 2019. Mr. Oron served as Chief Business Officer of BiomX Israel from January 2017 to October 2019. Prior to this position, he served in various roles at Evogene Ltd. (Nasdaq: EVGN), an agriculture biotechnology company, which utilizes a proprietary integrated technology infrastructure to enhance seed traits underlying crop productivity, from March 2006 to December 2016, including Executive Vice President of Strategy and Business Development and Executive Vice President of Corporate Development. Prior to joining Evogene, Mr. Oron served as Chief Executive Officer of ChondroSite Ltd., a biotechnology company that develops engineered tissue products in the field of orthopedics and as a senior project manager and strategic consultant at Israeli management consulting company POC Ltd. Mr. Oron holds an M.Sc. in Biology (bioinformatics) and a B.Sc. in Chemistry and Economics, both from Tel Aviv University.

***Dr. Merav Bassan*** has served as the Chief Development Officer of the Company since October 2019. Prior to this position, she served in various development roles at Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) between 2005 and 2019, including Vice President, Head of Translational Sciences, Specialty Clinical Development R&D from 2017 to 2019, Vice President, Pain and Global Internal Medicine, Project Leadership, Innovative Product Development, Global IR&D from 2015 to 2017, and Project Champion, Senior Director, Innovative Product Development, Global IR&D from 2009 to 2015. Dr. Bassan holds a B.Sc. in Biology, a M.Sc. in Human Genetics and a Ph.D. in Neurobiology from Tel Aviv University, and she completed a Post-Doctoral Fellowship in Neuroscience at Harvard Medical School at Harvard University.

**Directors**

The biography of Mr. Solomon is set forth above under the header "Executive Officers." The biographies of our non-employee directors are set forth below:

***Dr. Russell Greig*** has served as a director and chairman of the Board of the Company since October 2019. Dr. Greig has more than 35 years' experience in the pharmaceutical industry, with knowledge and expertise in research and development, business development and commercial operations. He spent the majority of his career at GlaxoSmithKline, or GSK, where he held a number of positions including GSK's President of Pharmaceuticals International from 2003 to 2008 and Senior Vice President Worldwide Business Development. From 2008 to 2010, Dr. Greig was also President of SR One, GSK's corporate venture group. He is currently Chairman of MedEye NV (formerly — Mint Solutions, The Netherlands) and eTheRNA immunotherapies NV (Belgium). In addition, Dr. Greig previously served on the boards of Sanifit (Spain) (acquired by Vifor Pharma AG (SWX: VIFN), Tigenix N.V. (acquired by Takeda Pharmaceutical Company Limited), Ablynx N.V. (acquired by Sanofi, France) and Merus N.V. (Nasdaq: MRUS). He was previously Chairman of Syntaxin Ltd (UK) (sold to Ipsen), Novagali Pharma S.A. (France) (acquired by Santen Pharmaceutical Co., Ltd.), and Isconova AB (Sweden) (acquired by Novavax, Inc. (Nasdaq: NVAX)). He served as acting Chief Executive Officer at Genocea Biosciences (Nasdaq: GNCA) and Isconova AB for an interim period. He was also a member of the Scottish Scientific Advisory Committee, reporting to the First Minister of Scotland.

We believe that Dr. Greig's qualifications to sit on our Board include his extensive board and leadership experience in business development and in drug research and development in the pharmaceutical industry.

***Dr. Gbola Amusa*** has served as a director of the Company since March 2018, and served as the Executive Chairman of the Company from March 2018 to October 2019. Dr. Amusa served as Executive Chairman and Chief Science Officer of Chardan Healthcare Acquisition 2 Corp. until its merger in September 2021 with Renovacor, Inc. (NYSE: RCOR). He is currently a director of Renovacor and Partner, Head of Healthcare Equity Research at Chardan Capital Markets LLC, or Chardan, since December 2014. At Chardan, he has established the healthcare vision by focusing on disruptive healthcare segments, such as gene therapy/genetic medicines, that have the highest potential for significant investment returns. Dr. Amusa was previously Managing Director, Head of European Pharma Research, and Global Pharma& Biotech Coordinator at UBS (from 2007 to 2013), where he oversaw 25 analysts. Prior to UBS, Dr. Amusa was a Senior Research Analyst and Head of European Pharma research at Sanford Bernstein. He started his career in finance at Goldman Sachs as an Associate in the Healthcare Investment Banking Group, where he worked on large transactions including the Amgen/Immunex merger. Additionally, Dr. Amusa was previously a Healthcare Finance & Strategy Consultant working with governments, companies, leading foundations and think tanks. He has also served as a member of the board of Alliance for Cancer Gene Therapy since September 2021. He holds an M.D. from Washington University Medical School, an M.B.A. with High Honors from the University of Chicago Booth School of Business, and a B.S.E. with Honors from Duke University.

We believe that Dr. Amusa's qualifications to sit on our Board include his board and management experience in the capital markets and the pharmaceutical and biotech industries.

***Jonas Grossman*** has served as a director of the Company from its formation in November 2017. Mr. Grossman served as President and Chief Executive Officer of Chardan Healthcare Acquisition 2 Corp. until its merger in September 2021 with Renovacor, Inc. (NYSE: RCOR). He is currently a director of Renovacor, and a Managing Partner and Head of Capital Markets for Chardan since December 2003 and has additionally served as President of Chardan since September 2015. With nearly two decades of transactional and special acquisition company expertise, Mr. Grossman has led or managed more than 400 transactions, including providing underwriting and business combination advisory services to more than 80 special purpose acquisition companies in a variety of industries. Mr. Grossman has been a founder and member of the board of six special purpose acquisition companies, of which on four he also has served as Chief Executive Officer and President. Since April 2020, Mr. Grossman has served as the President and Chief Executive Officer of Chardan Healthcare Acquisition 2 Corp. which announced its merger with Renovacor, Inc. in March 2021, and serves as the President and Chief Executive Officer of Chardan NexTech Acquisition 2 Corp. He also served as the Company's President and Chief Executive Officer from March 2018 until October 28, 2019, the date of the merger of CHAC Merger Sub Ltd. with and into BiomX Israel, whereby BiomX Israel became our wholly-owned subsidiary, or the Business Combination. Mr. Grossman was a founder and director of LifeSci Acquisition Corp. from March 2020 until the close of its business combination with Vincera Pharma, Inc. in December of 2020. He has served as a director to Ventoux CCM Acquisition Corp. since December 2020. Previously, from 2001 to 2003, Mr. Grossman worked at Ramius Capital Group, LLC, a global multi-strategy hedge fund where he served as Vice President and Head Trader. Mr. Grossman holds a B.A. in Economics from Cornell University and an M.B.A. from NYU's Stern School of Business. He has served on the board of directors for UNICEF since December 2016.

We believe that Mr. Grossman's qualifications to sit on our Board include his extensive board and management experience in business and capital markets.

***Dr. Alan Moses*** has served as a director of the Company since October 2020. Dr. Moses has been a Board member of Chemomab Therapeutics, Ltd. (Nasdaq: CMMB) since March 2021. Dr. Moses served as the Global Chief Medical Officer of Novo Nordisk A/S from 2013 until his retirement in 2018. Prior to that he served in various roles at Novo Nordisk A/S since 2004, beginning as Associate Vice President of Medical Affairs in the United States. Throughout his career, Dr. Moses has specialized in developing novel therapeutics and diagnostics for diabetes mellitus. He co-founded and directed the Clinical Investigator Training Program at Beth Israel Deaconess-Harvard Medical School-MIT. From 1998 to 2004, Dr. Moses served as Senior Vice President and Chief Medical Officer of the Joslin Diabetes Center with specific responsibility for the Joslin Clinic, and has served as a member of the Board of Joslin Diabetes Center since December 2021. Dr. Moses earned his MD from the Washington University School of Medicine in St. Louis, worked for three years at the National Institutes of Health, completed his clinical endocrine/diabetes training at Tufts New England Medical Center, and studied Health Care Strategy at Harvard Business School.

We believe that Dr. Moses' qualifications to sit on our Board include his extensive leadership experience in clinical development in the pharmaceutical industry.

***Lynne Sullivan*** has served as a director of the Company since November 2019. Ms. Sullivan has served as the Chief Financial Officer of UNITY Biotechnology, Inc. (Nasdaq: UBX) since August 2020. Prior to that she was the Chief Financial Officer of Compass Therapeutics, LLC, a biotechnology company, or Compass, where she worked from December 2018 to August 2019. Prior to Compass, Ms. Sullivan served as Biogen Inc.'s Senior Vice President of Finance from 2016 to December 2018, where she also served as Vice President of Tax and Corporate Finance from February 2015 to March 2016 and Vice President of Tax from April 2008 to February 2015. Prior to that, Ms. Sullivan was the Vice President Tax at EMD Serono and the Vice President of Tax North America at Merck KGaA. Ms. Sullivan is currently a member of the board of directors of Solid Biosciences Inc., a public life sciences company (Nasdaq: SLDB) and Inozyme Pharma, Inc. (Nasdaq: INZY). Ms. Sullivan was previously a member of the board of directors of resTORbio, Inc., a public biopharmaceutical company (Nasdaq: TORC) and Inheris Pharma. Ms. Sullivan was a Certified Public Account for over 20 years and was also a Tax Partner at Arthur Anderson, where she led the North East Region's Tax Consulting Practice for the firm. She received an M.S. in Taxation from Bentley University and a B.S.B.A. from Suffolk University.

We believe that Ms. Sullivan's qualifications to sit on our Board include her finance leadership and extensive board experience.

**Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all directors, officers and employees. The Code of Business Conduct and Ethics is available on our website at www.biomx.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code to any director or executive officer, we will promptly disclose the nature of the amendment or waiver on our website.

**Board Committees and Corporate Governance**

***Board Composition and Leadership Structure***

As of April 28, 2022, the Board is comprised of six members. There is currently one vacancy on the Board, created after Mr. Paul Sekhri resigned from our Board on March 29, 2022. The Board has a flexible policy with respect to the combination or separation of the offices of Chairman of the Board and Chief Executive Officer. Currently, Dr. Russell Greig serves as our independent Chairman, and Mr. Jonathan Solomon serves as our Chief Executive Officer. The Board believes that by having separate roles, the Chief Executive Officer is able to focus on the day-to-day business and affairs of the Company and the Chairman is able to focus on key strategic issues, board leadership and communication. While the Board believes this leadership structure is currently in the best interests of the Company and its stockholders, the Board also recognizes that future circumstances could lead it to combine these roles.

***Board Committees***

The Board has established three standing committees: the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee, each of which is composed solely of independent directors, and is described more fully below. Each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee operates pursuant to a written charter and each committee reviews and assesses the adequacy of its charter and submits its charter to the Board for approval. The charters for the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are all available on our website, www.biomx.com.

***Audit Committee***

Our Audit Committee engages the Company's independent accountants: reviews their independence and performance; reviews the Company's accounting and financial reporting processes and the integrity of its financial statements; reviews the audits of the Company's financial statements and the appointment, compensation, qualifications, independence and performance of the Company's independent auditors; reviews the Company's compliance with legal and reviews regulatory requirements; and reviews the performance of the Company's internal audit function and internal control over financial reporting.

The members of the Audit Committee are Ms. Lynne Sullivan, Dr. Gbola Amusa and Dr. Russell Greig, each of whom is an independent director under NYSE American's listing standards and satisfies the additional independence requirements of Rule 10A-3 of the Exchange Act. Ms. Lynne Sullivan is the Chairperson of the Audit Committee. The Board has determined that Ms. Sullivan qualifies as an "audit committee financial expert," as defined under the rules and regulations of the SEC.

***Compensation Committee***

Our Compensation Committee reviews annually the Company's corporate performance goals and objectives relevant to the Chief Executive Officer's compensation, evaluates the Chief Executive Officer's performance in light of such goals and objectives, determines and approves the Chief Executive Office's compensation level based on this evaluation; makes recommendations to the Board regarding approval, disapproval, modification, or termination of existing or proposed employee benefit plans; makes recommendations to the Board with respect to the compensation of our executive officers, other than the Chief Executive Officer, and directors; and administers the Company's incentive-compensation plans and equity-based plans. The Compensation Committee has the authority to delegate any of its responsibilities to subcommittees as it may deem appropriate in its sole discretion. The Chief Executive Officer of the Company may not be present during voting or deliberations of the Compensation Committee with respect to his compensation. The Company's executive officers do not play a role in suggesting their own salaries.

The members of the Compensation Committee are Dr. Alan Moses, Mr. Jonas Grossman and Dr. Russell Greig, each of whom is an independent director under NYSE American's listing standards. Dr. Alan Moses is the Chairperson of the Compensation Committee.

The Compensation Committee retained Aon Consulting Inc., or Aon, through its Radford subdivision, part of the Rewards Solutions practice at Aon, an independent compensation consultant, to provide advice with respect to executive, director and non-executive compensation for the fiscal year ended December 31, 2021. The Compensation Committee engaged Aon solely to collect and analyze data regarding executive, director and non-executive compensation at other companies comparable to us. Aon's primary responsibilities for the fiscal year ended December 31, 2021 included identifying our U.S. and Israel peer group companies, benchmarking the compensation of our directors, Chief Executive Officer, other executive officers and non-executive employees, assessing the competitive positioning of our executive compensation and providing recommendations to the Compensation Committee, which the Compensation Committee considered among the factors it reviewed when determining executive and director compensation. Aon provided peer based data on the competitiveness of our compensation program to the Compensation Committee in respect of the fiscal year ended December 31, 2021.

***Nominating and Governance Committee***

Our Nominating and Corporate Governance Committee is responsible for overseeing the selection of persons to be nominated to serve on the Board. Specifically, the Nominating and Corporate Governance Committee makes recommendations to the Board regarding the size and composition of the Board, establishes procedures for the director nomination process and screens and recommends candidates for election to the Board. On an annual basis, the Nominating and Corporate Governance Committee recommends for approval by the Board certain desired qualifications and characteristics for Board membership. Additionally, the Nominating and Corporate Governance Committee establishes and oversees the annual assessment of the performance of the Board as a whole and its individual members. The Nominating and Corporate Governance Committee will consider a number of qualifications relating to management and leadership experience, background and integrity and professionalism in evaluating a person's candidacy for membership on the Board. Although the Nominating and Corporate Governance Committee does not have a formal policy with regard to the consideration of diversity identifying nominees, the Nominating and Corporate Governance Committee may require certain skills or attributes, such as financial or accounting experience, to meet specific needs of the Board that arise from time to time and will also consider the overall experience and makeup of its members to obtain a broad and diverse mix of Board members. The Nominating and Corporate Governance Committee does not distinguish among nominees recommended by stockholders and other persons.

The members of the Nominating and Corporate Governance Committee are Dr. Russell Greig, Mr. Jonas Grossman and Ms. Lynne Sullivan, each of whom is an independent director under NYSE American's listing standards. Dr. Russell Greig is the Chairperson of the Nominating and Corporate Governance Committee.

**Item 11. Executive Compensation**

**Summary Compensation Table**

The following table sets forth the total compensation paid or accrued during the last two fiscal years with respect to (i) our Chief Executive Officer, (ii) our two other most highly compensated executive officers, who each earned more than $100,000 during the fiscal year ended December 31, 2021, and were serving as executive officers as of such date.

The following table presents information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for the years indicated.

| Name and Principal Position | Year | Salary ($)[1] | Bonus ($)[1] | Option Awards[2] ($)[2] | All Other Compensation ($)[1][3] | Total ($)[1] |
|---|---|---|---|---|---|---|
| Jonathan Solomon | 2021 | 391,077 | 193,231 | 653,966 | 96,723 | 1,334,997 |
| Chief Executive Officer | 2020 | 338,860 | 139,636 | 537,565 | 85,756 | 1,101,817 |
| Assaf Oron | 2021 | 248,314 | 52,953 | 144,176 | 50,770 | 496,213 |
| Chief Business Officer | 2020 | 204,309 | 57,264 | 138,893 | 43,416 | 443,882 |
| Dr. Merav Bassan | 2021 | 278,865 | 94,138 | 240,541 | 76,066 | 689,610 |
| Chief Development Officer | 2020 | 255,714 | 84,557 | 319,971 | 70,595 | 730,837 |

(1) All payments were originally made in New Israeli Shekels, or NIS, and were translated into USD using the annual average USD/NIS exchange rate for each fiscal year.

(2) Amounts in this column represent the grant date fair value of the option awards as computed in accordance with ASC 718, not including any estimates of forfeitures related to service-based vesting conditions. See Note 13.B. of the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2021 for a discussion of assumptions made by the Company in determining the grant date fair value of our option awards for the fiscal years ended December 31, 2021 and 2020. Note that the amounts reported in this column reflect the accounting cost for these stock options and do not reflect the actual economic value that may be realized by the non-employee directors upon the vesting of the stock options, the exercise of the stock options, or the sale of the Common Stock underlying such stock options.

(3) Amounts in this column represent additional payments for welfare benefits, disability insurance and other customary or mandatory social benefits to employees in Israel.

**Narrative Disclosure to the Summary Compensation Table**

***Option Awards***

Prior to the Business Combination, option awards were granted to our named executive officers under the 2015 Employee Stock Option Plan for Key Employees of BiomX Israel, or the 2015 Plan. Option awards granted to our named executive officers after the closing of the Business Combination are granted pursuant to the BiomX Inc. (formerly known as Chardan Healthcare Acquisition Corp.) 2019 Omnibus Long-Term Incentive Plan, or the 2019 Plan. In each case, one fourth of the options vest and become exercisable on the first anniversary of the grant date, and the remainder of the options vest and become exercisable in 12 equal quarterly instalments, subject to the named executive officer's continued employment; provided that the options will vest and become exercisable in the event the named executive officer is terminated within the twelve (12) month period following the occurrence of a Change in Control (as defined in the applicable grant agreement) as a result of an involuntary termination without Cause (as defined in the applicable grant agreement) or a voluntary termination with Good Reason (as defined in the applicable grant agreement). Subject to the terms of any employment agreement, the unexercised portion of these awards is generally forfeited by a participant on the date his or her employment is terminated other than due to death or disability. In the event of death or disability, the options become fully exercisable and remain exercisable for a period specified in the applicable award agreement.

***Bonus Awards***

We have an annual corporate and individual goal-setting and review process for our named executive officers that is the basis for the determination of potential annual bonuses. Each of our named executive officers is eligible for annual performance-based bonuses of up to a specific percentage of their salary, ranging from 40% to 50% subject to approval by the Board or the Compensation Committee. The performance-based bonus is tied to a set of specified corporate and/or individual goals and objectives reviewed and approved by the Board, such as clinical and development milestones, meeting budget and strategic goals, and we conduct an annual performance review to determine the attainment of such goals and objectives. Our management may propose bonus awards to the Board primarily based on such review process. The Compensation Committee makes the final determination of the achievement of both the specified corporate and strategic objectives and the eligibility requirements for and the amount of such bonus awards and recommends a bonus award payout to the Board for approval. For fiscal year 2021, bonuses were paid out based on advancing or development plans, the satisfaction of certain product candidate development milestones and strategic objectives.

***Employment Agreements***

Below are descriptions of our employment agreements with our named executive officers.

Jonathan Solomon

Pursuant to an employment agreement dated February 1, 2016, by and between BiomX Israel and Mr. Solomon, as the Chief Executive Officer of BiomX Israel, Mr. Solomon is entitled to a base salary of NIS 64,000, or approximately $19,500, per month, and an additional gross payment of NIS 16,000, or approximately $4,900, per month for up to 40 hours per month worked outside of normal business hours and normal business days (together with the base salary, Mr. Solomon's Salary). Starting April 1, 2021, Mr. Solomon was entitled to a base salary of NIS 82,400, or approximately $25,100, per month, and an overtime payment of NIS 20,600 or approximately $6,300, per month, and starting April 1, 2022, Mr. Solomon is entitled to a base salary of NIS 96,000, or approximately $30,000, per month, and an overtime payment of NIS 24,000 or approximately $7,500, per month.

BiomX Israel also makes customary contributions on Mr. Solomon's behalf to a pension fund or a managers insurance company, at Mr. Solomon's election, in an amount equal to 8.33% of his Salary, allocated to a fund for severance pay, and an additional amount equal to 5.00% of the Salary in case Mr. Solomon is insured through a managers insurance policy, or 6.50% of Mr. Solomon's Salary in case Mr. Solomon is insured through a pension fund, which shall be allocated to a provident fund or pension plan. In case Mr. Solomon chooses to allocate his pension payments to a managers insurance policy (and not a pension fund), the Company shall also insure him under a work disability insurance policy at the rate required to insure 100% of Mr. Solomon's Salary and for this purpose will contribute an amount of up to 2.50% of Mr. Solomon's Salary insured in such insurance policy for disability insurance in a policy and/or insurance company. These payments are intended to be in lieu of statutory severance pay that Mr. Solomon would otherwise be entitled to receive from BiomX Israel in accordance with Severance Pay Law 5723-1963, or the Severance Pay Law. BiomX Israel also contributes 7.50% of Mr. Solomon's monthly salary to a recognized educational fund. BiomX Israel also reimburses Mr. Solomon for automobile maintenance and transportation expenses of NIS 2,000, or $610 per month. Mr. Solomon is also entitled to non-statutory 12 months severance (including social benefits), upon either (i) resignation with a good reason, or (ii) termination without cause (as the terms good reason and cause would be defined by the parties, consistent with our past practice), provided that Mr. Solomon waives all claims and continues to comply with the other terms of his employment agreement.

Assaf Oron

Pursuant to an employment agreement dated January 1, 2017, by and between BiomX Israel and Mr. Oron, he serves as our Chief Business Officer. Mr. Oron is entitled to a base salary of NIS 31,500, or approximately $9,692, per month, and an additional gross payment of NIS 8,500, or approximately $2,615, per month for up to 40 hours per month worked outside of normal business hours and normal business days (together with the base salary, Mr. Oron's Salary. Starting April 1, 2021, Mr. Oron's base salary is NIS 51,040 or approximately $17,600, per month, and an additional gross payment of NIS 12,760 or approximately $4,400, per month. Starting March 1, 2022, Mr. Oron's employment agreement was amended to reflect 25% of full time. All components of his employment were adjusted proportionally.

BiomX Israel also makes customary contributions on Mr. Oron's behalf to a pension fund or a managers insurance company, at Mr. Oron's election, in an amount equal to 8.33% of Mr. Oron's Salary, allocated to a fund for severance pay, and an additional amount equal to 5.00% of Mr. Oron's Salary in case Mr. Oron is insured through a managers insurance policy, or 6.50% of Mr. Oron's Salary in case Mr. Oron is insured through a pension fund, which shall be allocated to a provident fund or pension plan. In case Mr. Oron chooses to allocate his pension payments to a managers insurance policy (and not a pension fund), the Company shall also insure him under a work disability insurance policy at the rate required to insure 75% of Mr. Oron's Salary and for this purpose will contribute an amount of up to 2.50% of Mr. Oron's Salary insured in such insurance policy for disability insurance in a policy and/or insurance company. These payments are in lieu of statutory severance pay that Mr. Oron would otherwise be entitled to receive from BiomX Israel in accordance with the Severance Law. BiomX Israel also contributes 7.50% of Mr. Oron's monthly Salary (not to exceed NIS 15,712, or approximately $4,834) to a recognized educational fund. The Company reimburses Mr. Oron for automobile maintenance and transportation expenses of NIS 2,500, or approximately $762, per month. Mr. Oron is also entitled to non-statutory 9 months severance (including social benefits), upon either (i) resignation with a good reason, or (ii) termination without cause (as the terms good reason and cause would be defined by the parties, consistent with our past practice), provided that Mr. Oron waives all claims and continues to comply with the other terms of his employment agreement.

Dr. Merav Bassan

Pursuant to an employment agreement dated August 26, 2019, by and between BiomX Israel and Dr. Bassan, as the Chief Development Officer of BiomX Israel, Dr. Bassan is entitled to a base salary of NIS 56,000, or approximately $17,230, per month, and an additional gross payment of NIS 14,000, or approximately $4,307, per month for up to 40 hours per month worked outside of normal business hours and normal business days (together with the base salary, Dr. Bassan's Salary). Starting April 1, 2021, Dr. Bassan's base salary was NIS 57,600 or approximately $17,600, per month, and an additional gross payment of NIS 14,400 or approximately $4,400, per month. Starting April 1, 2022, Dr. Bassan is entitled to a base salary of NIS 60,400, or approximately $18,900, per month, an additional gross payment of NIS 15,100 or approximately $4,700, per month.

BiomX Israel also makes customary contributions on Dr. Bassan's behalf to a pension fund or a managers insurance company, at Dr. Bassan's election, in an amount equal to 8.33% of Dr. Bassan's Salary, allocated to a fund for severance pay, and an additional amount equal to 7.30% of Dr. Bassan's Salary in case Dr. Bassan is insured through a managers insurance policy, or 6.50% of Dr. Bassan's Salary in case Dr. Bassan is insured through a pension fund, which shall be allocated to a provident fund or pension plan. In case Dr. Bassan chooses to allocate her pension payments to a managers insurance policy (and not a pension fund), the Company shall also insure her under a work disability insurance policy at the rate required to insure 75% of Dr. Bassan's Salary and for this purpose will contribute an amount of up to 2.50% of the Salary insured in such insurance policy for disability insurance in a policy and/or insurance company. These payments are in lieu of statutory severance pay that Dr. Bassan would otherwise be entitled to receive from BiomX Israel in accordance with the Severance Law. BiomX Israel also contributes 7.50% of Dr. Bassan's monthly Salary to a recognized educational fund. The Company reimburses Dr. Bassan for automobile maintenance and transportation expenses of NIS 2,500, or approximately $762, per month. Dr. Bassan is also entitled to non-statutory 9 months severance (including social benefits), upon either (i) resignation with a good reason, or (ii) termination without cause (as the terms good reason and cause would be defined by the parties, consistent with our past practice), provided that Dr. Bassan waives all claims and continues to comply with the other terms of her employment agreement.

**Outstanding Equity Awards at 2021 Fiscal Year-End**

The following table provides information regarding equity awards held by the named executive officers that were outstanding as of December 31, 2021:

| | Option Awards | | | | |
|---|---|---|---|---|---|
| **Name** | **Grant Date** | **Number of Securities Underlying Unexercised Options Exercisable[(1)] (#)** | **Number of Securities Underlying Unexercised Options Unexercisable[(1)] (#)** | **Option Exercise Price ($)** | **Option Expiration Date** |
| Jonathan Solomon | 11/13/2016 | 167,434 | - | 0.54 | 01/07/2027 |
| | 03/26/2017 | 182,133 | - | 1.69 | 03/26/2027 |
| | 05/22/2018 | 176,503 | 25,215 | 1.97 | 05/21/2028 |
| | 03/29/2019 | 195,733 | 88,968 | 2.03 | 03/29/2029 |
| | 03/25/2020 | 63,000 | 81,000 | 6.21 | 03/25/2030 |
| | 03/30/2021 | - | 152,000 | 7.02 | 03/30/2031 |
| Dr. Merav Bassan | 10/10/2019 | 94,999 | 94,998 | 10.00 | 10/10/2029 |
| | 03/30/2021 | - | 47,500 | 7.02 | 03/30/2031 |
| Assaf Oron | 03/26/2017 | 155,363 | - | 1.69 | 03/26/27 |
| | 05/22/2018 | 72,337 | 10,330 | 1.97 | 05/21/28 |
| | 03/29/2019 | 32,289 | 14,677 | 2.03 | 03/29/29 |
| | 03/25/2020 | 13,782 | 17,718 | 6.21 | 03/25/30 |
| | 03/30/2021 | - | 33,250 | 7.02 | 03/30/31 |

(1) Unless otherwise indicated, options vest and become exercisable as follows: 25% of the options on the first anniversary of the "vesting commencement date" (as defined in the applicable notice of option grant) and, thereafter, in 12 equal quarterly installments of 6.25% each.

**Compensation of Directors**

We maintain a non-employee director compensation policy, pursuant to which each non-employee director receives an annual retainer of $35,000. In addition, our non-employee directors receive the following cash compensation for board services, as applicable:

- the chairman of the Board receives an annual retainer of $100,000 (inclusive of annual committee chairmanship and membership);
- each member of our Audit, Compensation and Nominating and Corporate Governance Committees, other than the chairperson, receives an additional annual retainer of $7,500, $5,000 and $4,000, respectively; and
- each chairperson of our Audit, Compensation and Nominating and Corporate Governance Committees receives an additional annual retainer of $15,000, $10,000 and $8,000, respectively.

We pay all amounts in quarterly installments. We also reimburse each of our directors for their reasonable travel, lodging and other out-of-pocket expenses incurred relating to their attendance at Board and committee meetings.

Each non-employee director also receives an annual award of options to purchase our Common Stock. One-fourth of each Annual Option Award vests on the first anniversary of the date of grant, and the remainder of the annual option award vests in 12 equal quarterly installments, subject to such director's continued service on the Board. The Company's policy is to grant options based, among other things, on recommendations of a compensation consultant. In 2021, the Company granted 15,200 options to each non-employee director and 30,400 to the Chairman of the Board.

The following table sets forth information concerning compensation accrued or paid to our independent, non-employee directors during the year ended December 31, 2021 for their service on our Board. Mr. Jonathan Solomon, a director who is also our employee, received no additional compensation for his service as director and is not set forth in the table below:

| Name | Fees earned or paid in cash ($) | Option Awards[(2)(3)] | All other compensation[(4)] | Total ($) |
|---|---|---|---|---|
| Dr. Russell Greig | 100,500 | 117,584 | — | 218,084 |
| Dr. Gbola Amusa | 42,500 | 58,792 | — | 101,292 |
| Jonas Grossman | 44,000 | 58,792 | — | 102,792 |
| Dr. Alan Moses | 35,000 | 71,966 | 25,000 | 131,966 |
| Paul Sekhri[(1)] | 45,000 | 71,966 | — | 116,966 |
| Lynne Sullivan | 54,000 | 58,792 | — | 112,792 |
| | 321,000 | 437,892 | 25,000 | 783,892 |

(1) Effective as of March 29, 2022, this director resigned and no longer serves on the Board.

(2) Amounts in this column represent the grant date fair value of the option awards as computed in accordance with ASC 718, not including any estimates of forfeitures related to service-based vesting conditions. See Note 13.B. of the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2021 for a discussion of assumptions made by the Company in determining the grant date fair value of our option awards for the fiscal year ended December 31, 2021. Note that the amounts reported in this column reflect the accounting cost for these stock options and do not reflect the actual economic value that may be realized by the non-employee directors upon the vesting of the stock options, the exercise of the stock options, or the sale of the Common Stock underlying such stock options.

(3) As of December 31, 2021, we had outstanding grants to our non-executive directors aggregating 218,400 options of which 43,000 were exercisable or vested, as the case may be, as follows:

| Name | Total of options granted | Total of options exercisable and vested |
|---|---|---|
| Russell Greig | 62,400 | 14,000 |
| Dr. Gbola Amusa | 31,200 | 7,000 |
| Jonas Grossman | 31,200 | 7,000 |
| Dr. Alan Moses | 31,200 | 4,000 |
| Paul Sekhri | 31,200 | 4,000 |
| Lynne Sullivan | 31,200 | 7,000 |
| **Total** | 218,400 | 43,000 |

(4) Amounts in this column represent payments made to Dr. Moses as compensation for consulting services to BiomX Israel. Starting January 1, 2021 Dr. Moses provides additional consulting services to the Company for an annual fee of $25,000.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

**Securities Authorized for Issuance Under Equity Compensation Plans**

We have two equity incentive plans, the 2015 Employee Stock Option Plan, or the 2015 Plan, and the Chardan Healthcare Acquisition Corp. 2019 Equity Incentive Plan, or the 2019 Plan. In October 2019, in connection with the Business Combination, we assumed the 2015 Plan with respect to each outstanding equity award thereunder. Although no shares of our Common Stock are available for future issuance under the 2015 Plan, the 2015 Plan will continue to govern outstanding awards granted thereunder. As of December 31, 2021, options to purchase 2,466,533 shares of our Common Stock remained outstanding under the 2015 Plan.

The 2019 Plan was adopted by the Board of Directors and approved by our stockholders in connection with the Business Combination. As of December 31, 2021, there were 216,036 shares of our Common Stock available for issuance under the 2019 Plan. The aggregate number of shares of our Common Stock available for issuance pursuant to the 2019 Plan automatically increases on January 1 of each year, for a period of not more than ten years, commencing on January 1, 2020 and ending on (and including) January 1, 2029, in an amount equal to 4% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year. Accordingly, on January 1, 2022, 1,190,129 additional shares of our Common Stock were made available for issuance pursuant to the 2019 Plan.

For additional information regarding the 2015 Plan and the 2019 Plan, as of December 31, 2021, please see the Original Report – Part II – Item 8 – Financial Statements and Supplemental Data – Notes to consolidated financial statements – Note 12B – Stock-Based Compensation.

| | Equity Compensation Plan Information December 31, 2021 | | |
|---|---|---|---|
| Plan category | Number of securities to be issued upon exercise of outstanding options and restricted stock (a) | Weighted-average exercise price of outstanding options and restricted stock (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
| Equity compensation plans approved by security holders | 1,618,012 | 6.64 | 216,036 |
| Equity compensation plans not approved by security holders | 2,466,533 | 2.19 | |
| Total | 4,084,545 | 3.95 | 216,036 |

**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth information regarding the beneficial ownership of our Common Stock as of April 26, 2022 (except as otherwise indicated) based on information obtained from the persons named below, with respect to the beneficial ownership of our Common Stock, by (i) each person known by us to be the beneficial owner of more than 5% of our outstanding Common Stock; (ii) each of our named executive officers and directors; and (iii) all our executive officers and directors as a group. Information with respect to beneficial ownership is based on information furnished to us by each director, executive officer or stockholder who holds more than 5% of our outstanding Common Stock, and Schedules 13G or 13D filed with the SEC, as the case may be, and includes shares of our Common Stock which each beneficial owner has the right to acquire within 60 days of April 26, 2022. Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all Common Stock beneficially owned by them. We have based our calculation of beneficial ownership on 29,780,409 shares of our Common Stock outstanding as of April 26, 2022.

| Name and Address of Beneficial Owner[1] | Amount and Nature of Beneficial Ownership | Percent of Class |
|---|---|---|
| Chidozie Ugwumba[2]<br>c/o SymBiosis CapitalManagement, LLC<br>609 SW 8th St., Suite 365<br>Bentonville, AR 72712 | 5,512,846 | 18.5% |
| MMCAP International Inc. SPC[3]<br>c/o Mourant Governance Services (Cayman) Limited<br>94 Solaris Avenue<br>Camana Bay, P.O. Box 1348<br>Grand Cayman, KY1-1108, Cayman Islands | 2,115,639 | 7.1% |
| Johnson & Johnson Innovation – JJDC, Inc.[4]<br>Johnson & Johnson Innovation – JJDC, Inc.<br>410 George Street<br>New Brunswick, NJ 08901 | 2,133,402 | 7.2% |
| OrbiMed Advisors Israel Limited<br>OrbiMed Israel GP Ltd.<br>OrbiMed Israel Partners, Limited Partnership[5]<br>89 Medinat Hayehudim St.<br>Building E<br>Herzliya 4614001 Israel | 3,188,489 | 10.7% |
| **Directors and Named Executive Officers** | | |
| Jonathan Solomon[6] | 1,380,736 | 4.6% |
| Dr. Russell Greig[7] | 68,963 | * |
| Dr. Gbola Amusa[8] | 450,916 | 1.5% |
| Jonas Grossman[9] | 790,262 | 2.7% |
| Lynne Sullivan[10] | 53,075 | * |
| Dr. Alan Moses[11] | 39,950 | * |
| Dr. Merav Bassan[12] | 337,497 | 1.1% |
| Assaf Oron[13] | 349,746 | 1.2% |
| **All directors and executive officers as a group (9 persons)** | 3,596,958 | 12.1% |

* Less than 1%.

(1) Unless otherwise indicated, the business address of each of the individuals is c/o BiomX Inc., 22 Einstein St., 5th Floor, Ness Ziona 7414003, Israel.

(2) Based solely on information contained in Form 13G filed with the SEC on February 14, 2022.

(3) Based solely on information contained in Form 13G/A filed with the SEC on February 4, 2022. Such 13G/A was also jointly filed by MM Asset Management Inc. with an address at 161 Bay Street,
TD Canada Trust Tower Ste 2240, Toronto, ON M5J 2S1 Canada.

(4) Based solely on information contained in Form 13G filed with the SEC on November 26, 2019.Johnson & Johnson Innovation-JJDC, Inc. has voting and dispositive power over 2,133,402 shares of common stock.

(5) Represents 1,672,150 shares of Common Stock held directly by OrbiMed Israel Partners, Limited Partnership, or OIP LP, and 641,339 shares of Common Stock held directly by OrbiMed Israel Incubator L.P., or OII LP. OrbiMed Israel BioFund GP Limited Partnership, or BioFund GP LP, is the general partner of each of OIP LP and OII LP, and OrbiMed Israel GP Ltd., or Israel GP, is the general partner of BioFund GP LP. OrbiMed Advisors Israel Limited, or Advisors Israel Ltd., is the majority shareholder of Israel GP. As a result, Advisors Israel Ltd and Israel GP may be deemed to have shared voting and investment power over all of the shares of Common Stock held by each of OIP LP and OII LP, and both Advisors Israel Ltd and Israel GP may be deemed to directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the shares held by each of OIP LP and OII LP. Advisors Israel Ltd exercises this investment power through an investment committee comprised of Carl L. Gordon, Jonathan T. Silverstein, Nissim Darvish, Anat Naschitz, and Erez Chimovits, each of whom disclaims beneficial ownership of the shares held by OIP LP and OII LP. Based solely on information contained in Form 13D filed with the SEC on November 7, 2019.

(6) Consists of 862,204 options that are exercisable and 21,608 additional options that will become exercisable within 60 days of April 26, 2022.
(7) Consists of 3,750 shares of Common Stock, 2,813 warrants (entitling the holder to acquire up to 2,813 shares of Common Stock), 23,600 options that are exercisable and 2,000 additional options that will become exercisable within 60 days of April 26, 2022.
(8) Consists of 262,871 shares of Common Stock, 294,940 warrants (entitling the holder to acquire up to 156,845 shares of Common Stock), 11,800 options that are exercisable and 1,000 additional options that will become exercisable within 60 days of April 26, 2022.
(9) Consists of 372,717 shares of Common Stock, 744,564 warrants (entitling the holder to acquire up to 386,345 shares of Common Stock), 11,800 options that are exercisable and 1,000 additional options that will become exercisable within 60 days of April 26, 2022.
(10) Consists of 12,500 shares of Common Stock, 9,375 warrants (entitling the holder to acquire up to 9,375 shares of Common Stock), 11,800 options that are exercisable and 1,000 additional options that will become exercisable within 60 days of April 26, 2022.
(11) Consists of 9,800 options that are exercisable.
(12) Consists of 130,624 options that are exercisable.
(13) Consists of 292,155 options that are exercisable and 7,132 additional options that will become exercisable within 60 days of April 26, 2022.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Other than compensation, termination, change in control and other arrangements, which are described in Item 11 – Executive Compensation and Item 12 – Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, our only related-person transaction since January 1, 2021 consisted of a Securities Purchase Agreement we entered into on July 26, 2021 with certain institutional investors, all of the Company's directors and certain executive officers for the sale of an aggregate of 3,750,000 shares of Common Stock and warrants to purchase an aggregate of 2,812,501 shares of Common Stock in a registered direct offering, for gross proceeds of $15.0 million, before deducting placement agent fees and offering expenses and assuming that none of the warrants are exercised. The securities were sold at price of $4.00 per share and an accompanying warrant to purchase 0.75 of a share of the Company's Common Stock at an exercise price of $5.00 per share. The warrants will be exercisable six months after the date of issuance and will expire five years from the date such warrant first becomes exercisable. The warrants issued were classified as equity in accordance with ASC 815-40. The securities were offered pursuant to the Company's effective registration statement on Form S-3. All proceeds were received as of July 28, 2021. Of these proceeds, an aggregate of 125,000 shares of Common Stock and 93,750 warrants were sold to directors and certain executive officers for gross proceeds of $500,000.

**Director Independence**

The NYSE American requires that a majority of the Board be composed of "independent directors," which is defined generally as a person other than an officer or employee of the Company or its subsidiaries or any other individual having a relationship that, as determined by the Board, would interfere with the exercise of his or her objective judgment and will meet the required standards for independence, as established by the applicable rules and regulations of the NYSE American and the SEC.

Dr. Gbola Amusa, Dr. Russell Greig, Mr. Jonas Grossman, Dr. Alan Moses and Ms. Lynne Sullivan are our independent directors. Our independent directors have regularly scheduled meetings at which only independent directors are present.

At least annually, the Board evaluates all relationships between us and each director considering relevant facts and circumstances for the purposes of determining whether a material relationship exists that might signal a potential conflict of interest or otherwise interfere with such director's ability to satisfy his or her responsibilities as an independent director. Based on this evaluation, our Board will make an annual determination of whether each director is independent within the meaning of NYSE American and the SEC independence standards.

**Item 14. Principal Accounting Fees and Services**

The following is a summary and description of fees billed by us to Kesselman & Kesselman, Certified Public Accountants (Isr.) for the fiscal year ended December 31, 2021 and to Brightman Almagor Zohar & Co. for the fiscal year ended December 31, 2020.

| | Fiscal year ended December 31, 2021 | Fiscal year ended December 31, 2020 |
|---|---|---|
| Audit fees[(1)] | $ 108,000 | $ 70,000 |
| Audit-related fees[(2)] | $ 63,612 | $ 25,000 |
| Tax fees[(3)] | $ — | $ 2,700 |
| All other fees | $ — | $ — |
| **Total fees** | **$ 171,612** | **$ 97,700** |

**(1)** **Audit Fees** include fees for professional services rendered for the quarterly reviews of the interim consolidated financial statements and the annual audit of our consolidated financial statements included in our Annual Report on Form 10-K.

**(2)** **Audit-Related Fees** include fees for services that were reasonably related to performance of the audit of the annual consolidated financial statements for the fiscal year, other than Audit Fees, such as for services in connection with an Open Market Sale Agreement [SM] we entered with Jefferies LLC on December 4, 2020, our July equity offering and a registration statement filed for the re-sale of certain shares of common stock by a selling stockholder.

**(3)** **Tax Fees** include fees for tax compliance and tax advice.

**Pre-Approval Policies and Procedures**

The Audit Committee approves all audit and pre-approves all non-audit services provided by our independent registered public accounting firm before it is engaged by us to render non-audit services. These services may include audit-related services, tax services and other services.

The pre-approval requirement set forth above does not apply with respect to non-audit services if:

- all such services do not, in the aggregate, amount to more than 5% of the total fees paid by us to our independent registered public accounting firm during the fiscal year in which the services are provided;
- such services were not recognized as non-audit services at the time of the relevant engagement; and
- such services are promptly brought to the attention of and approved by the Audit Committee (or its delegate) prior to the completion of the annual audit.

**Pre-Approval Policies and Procedures**

The Audit Committee approves all audit and pre-approves all non-audit services provided by our independent registered public accounting firm before it is engaged by us to render non-audit services. These services may include audit-related services, tax services and other services.

The pre-approval requirement set forth above does not apply with respect to non-audit services if:

- all such services do not, in the aggregate, amount to more than 5% of the total fees paid by us to our independent registered public accounting firm during the fiscal year in which the services are provided;
- such services were not recognized as non-audit services at the time of the relevant engagement; and
- such services are promptly brought to the attention of and approved by the Audit Committee (or its delegate) prior to the completion of the annual audit.

**Item 15. Exhibits, Financial Statement Schedules**

The exhibits listed in the following Index to Exhibits are filed or incorporated by reference a part of this report.

| Exhibit No. | Description |
|---|---|
| 10.1 | Employment Agreement, dated February 1, 2016, between BiomX Ltd. (formerly MBcure Ltd.) and Jonathan Solomon. |
| 10.2 | Employment Agreement, dated August 26, 2019, between BiomX Ltd. and Merav Bassan. |
| 10.3 | Employment Agreement, dated January 1, 2017, between BiomX Ltd. (formerly MBcure Ltd.) and Assaf Oron. |
| 31.1 | Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL) |

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOMX INC.

Dated: May 2, 2022

By: /s/ Jonathan Solomon
Name: Jonathan Solomon
Title: Chief Executive Officer

# CORPORATE INFORMATION

***Executive Officers***

Jonathan Solomon
Chief Executive Officer

Marina Wolfson
Chief Financial Officer

Dr. Merav Bassan
Chief Development Officer

Mr. Assaf Oron
Chief Business Officer

***Directors***

Dr. Russell Greig
Chairman of the Board

Jonathan Solomon
Chief Executive Officer of BiomX Inc.

Dr. Gbola Amusa
Partner, Director of Research and Head of Healthcare Equity Research of Chardan Capital Markets LLC

Jonas Grossman
Partner and Head of Capital Markets of Chardan Capital Markets LLC

Dr. Alan Moses
Consultant

Lynne Sullivan
Chief Financial Officer of UNITY Biotechnology, Inc.

***Corporate Address***

22 Einstein St., Floor 4
Ness Ziona 7414003, Israel.

***Independent Auditors for 2021 Fiscal Year***

Kesselman & Kesselman Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited

***Counsel***

Sullivan & Worcester LLP
One Post Office Square
Boston, Massachusetts 02109
U.S.A.

Gornitzky & Co.
20 Haharash St.
Tel Aviv 6761310
Israel

***Transfer Agent***

Continental Stock Transfer & Trust Company, Inc.
1 State Street
30th Floor
New York, NY 10004
U.S.A.

***Stock Market Information***

BiomX's shares of common stock are traded on the NYSE American and the Tel Aviv Stock Exchange under the symbol 'PHGE'.

***Annual Meeting***

The Annual Meeting of Stockholders will be held at 8:00 a.m., Eastern Time, on August 24, 2022, entirely online.

***Annual Report on Form 10-K***

BiomX's Annual Report on Form 10-K, as amended, (without exhibits) is available free of charge by writing to BiomX at the address set forth above. You can also obtain a copy of the filing by going to the following website: https://ir.biomx.com/sec-filings/annual-reports.

***Website***

http://www.biomx.com